Guiding Opinions on the Standardized Development of Modern Pharmaceutical Logistics[1]

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Article 1

In order to promote the standardized development of a modern pharmaceutical logistics system and facilitate high-quality development of the pharmaceutical distribution industry, these Guiding Opinions are formulated in accordance with the *Administrative Measures for the Supervision of the Quality of Pharmaceutical Distribution and Use*, the *Good Supply Practice for Pharmaceutical Distribution* (hereinafter referred to as the "GSP"), and other relevant regulatory requirements.

Article 2

These Guiding Opinions set forth basic requirements regarding pharmaceutical modern logistics facilities and equipment for applicants seeking to establish pharmaceutical wholesale enterprises (hereinafter referred to as "wholesale enterprises") and for third-party pharmaceutical logistics enterprises engaged in commissioned storage and transportation of pharmaceuticals (hereinafter referred to as "third-party logistics enterprises").

These Opinions shall also serve to guide existing enterprises in gradually meeting the pharmaceutical modern logistics requirements set forth herein.

For the purposes of these Guiding Opinions, "third-party logistics enterprises" refer to enterprises entrusted by holders of marketing authorization for pharmaceuticals, pharmaceutical manufacturers, pharmaceutical distribution enterprises, and other consignors, to store and transport pharmaceuticals.

Article 3

Pharmaceutical modern logistics refers to logistics systems that, on the basis of meeting the requirements of the GSP, are equipped with facilities and equipment suitable for pharmaceutical storage and capable of performing modern logistics operations such as inbound receipt,

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inspection, transfer, sorting, shelving, outbound delivery, verification, consolidation, and transportation. Such systems shall be supported by independent computerized information management systems and an end-to-end quality control and information traceability system covering pharmaceutical receipt, inspection, storage, maintenance, outbound operations, and transportation.

Pharmaceutical modern logistics shall achieve scalability, intensification, digitalization, intelligence, and traceability throughout the logistics process.

Article 4

Enterprises shall, in accordance with the unified pharmaceutical information traceability standards and specifications formulated by the National Medical Products Administration, establish an information-based traceability management system appropriate to the types and scale of pharmaceuticals stored and transported.

Enterprises shall implement pharmaceutical traceability responsibilities, maintain accurate records of business and logistics activities, and ensure that the source of pharmaceuticals in distribution and storage is traceable, their destination trackable, and responsibility identifiable.

Article 5

Enterprises shall, in accordance with applicable laws, regulations, and the provisions of the GSP, establish and improve a quality management system for pharmaceutical modern logistics, set up organizational structures and positions appropriate to such logistics operations, formulate system documents, job responsibilities, and operating procedures, and allocate qualified personnel engaged in pharmaceutical distribution and quality management, so as to ensure that the entire pharmaceutical distribution process continuously complies with legal requirements.

Article 6

In addition to compliance with the GSP, the quality management system established by enterprises shall also include the following:

1.Logistics management;

2.Data management;

3.Quality assessment management for entrusted storage and transportation;

4.Cybersecurity assurance management;

5.Emergency response plans for warehousing and transportation incidents;

6.Other matters that shall be prescribed.

Article 7

Enterprises shall establish corresponding organizational structures and posts in accordance with their business scope and scale of operations, and shall allocate personnel possessing the requisite technical qualifications and competencies.

Personnel engaged in logistics quality management, inspection and acceptance, maintenance, transportation, and related functions shall receive training on laws and regulations relating to pharmaceutical storage and transportation.

The legal representative and principal responsible person of an enterprise shall assume overall responsibility for pharmaceutical business activities and shall ensure that the quality responsible person is able to fully perform quality management functions. The quality responsible person shall have decision-making authority over quality management matters and shall ensure continuous compliance of the entire pharmaceutical business process with statutory requirements.

Article 8

The legal representative, principal responsible person, quality responsible person, and other personnel engaged in pharmaceutical business and quality management shall meet the qualification requirements specified in the Good Supply Practice ("GSP"), and shall not fall under any circumstances prohibited from engaging in pharmaceutical business activities as stipulated in the *Pharmaceutical Administration Law of the People's Republic of China*, the *Vaccines Administration Law of the People's Republic of China*, the *Measures for the Administration of Licensed Pharmacist Registration*, or other relevant laws and regulations.

Article 9

Enterprises shall establish logistics management institutions appropriate to their pharmaceutical modern logistics business and shall allocate logistics management personnel and computer management personnel.

Logistics management personnel shall possess at least a junior college degree or above in logistics-related disciplines, or nationally recognized vocational qualifications (including professional titles) in logistics-related fields.

Computer management personnel shall possess at least a junior college degree or above in computer-related disciplines, or nationally recognized vocational qualifications (including professional titles) in computer-related fields.

Enterprises shall employ personnel responsible for equipment operation and maintenance with the corresponding nationally recognized qualifications for employment.

Article 10

Enterprises shall possess premises, warehouses, logistics equipment, and transportation vehicles that comply with the requirements of the GSP and are appropriate to their business scope and scale, and shall have the storage and distribution capacity necessary to undertake modern pharmaceutical logistics operations.

Article 11

The site selection, design, layout, construction, renovation, and maintenance of warehouses shall comply with pharmaceutical storage requirements and shall prevent contamination, cross-contamination, mix-ups, and errors.

Warehouses shall be buildings that comply with relevant national standards and shall be self-operated warehouses.

The internal and external environment of warehouses shall be clean and free from pollution sources, and shall maintain relative independence from surrounding enterprises, residential areas, or facilities. The warehouse buildings shall be free from odors, high temperature, steam, harmful gases, wastewater, dust, or other factors that may affect the quality and safety of pharmaceutical storage.

Business premises and warehouses shall be effectively physically separated. Warehouses shall be strictly separated from surrounding environments and from the flow of personnel and logistics of other enterprises, and shall be equipped with anti-theft, video surveillance, and other relevant facilities and equipment.

Article 12

Warehouses shall be equipped with functional zones appropriate to operational needs, capable of meeting workflow requirements and logistics scale. The specific requirements are as follows:

1.Warehouses shall include ambient-temperature storage areas and cool storage areas compliant with pharmaceutical storage requirements (where ambient-temperature and cool-temperature medicines are co-stored in the same warehouse, temperature control shall be maintained at 10°C–20°C), as well as cold storage facilities and other storage areas with special temperature requirements. Non-conforming pharmaceuticals shall be stored in designated quarantine areas, and returned pharmaceuticals shall be stored in clearly marked storage areas or zones.

2.The areas for receipt and inspection, sorting and verification, and consolidation and distribution shall be of sufficient size to meet modern logistics operational needs. Except for special-controlled medicines, anabolic agents, peptide hormones, and refrigerated or frozen pharmaceuticals, for which outbound verification and consolidation areas shall be established within dedicated warehouses, the outbound verification and consolidation areas for other pharmaceuticals shall be centrally arranged.

3.Warehouses shall include storage areas for loose units and storage areas for full-case goods, appropriate to the scale of operations.

4.Warehouses shall be equipped with facilities and a computer control room (or area) capable of enabling remote monitoring functions, including temperature and humidity monitoring within warehouses, video surveillance of storage areas, temperature and location monitoring of refrigerated transport vehicles, and alarm functions for abnormal conditions.

Article 13

Enterprises shall be equipped with facilities and equipment that match the needs of modern pharmaceutical logistics operations, including receiving, inspection, transfer, shelving, sorting, outbound shipping, checking, and consolidation. These facilities and equipment should ensure smooth and continuous operations and reduce the risk of mix-ups and errors. Materials used must not release toxic or harmful substances, should resist mold and moisture, and must not affect drug quality or safety.

1.Inbound management equipment. Under the coordination of a warehouse management system, and depending on space, storage method, and distance, suitable automated and intelligent logistics equipment such as conveyor systems, automated storage and retrieval systems, automated guided vehicles, and shuttle systems may be used. This equipment helps automatically assign locations, identify items, and determine storage positions. Electric forklifts may be used when needed.

2. Storage equipment. Pallets, partition shelves, flow racks, high racks, or automated storage systems may be used. Goods must be properly separated from each other, and kept off the floor and away from walls. Barcodes should be used for pallets and shelves so each storage location has a unique code, managed by the warehouse system.

3. Internal transport equipment. Equipment suitable for the scale of operations should be provided, such as conveyor systems, automated storage and retrieval systems, automated guided vehicles, shuttle systems, and electric forklifts if necessary. These should cover storage areas, picking areas, outbound checking areas, and consolidation and distribution areas to ensure smooth operations and reduce errors.

4. Information identification equipment. This includes barcode printing and scanning devices, RFID technology, and electronic picking systems or similar tools.

5. Temperature and humidity control equipment. Air-conditioning systems and other equipment should be installed to control temperature and humidity in the warehouse and allow air exchange between indoors and outdoors, according to required standards.

6. Video surveillance equipment. A surveillance system should cover all main working areas in the warehouse. It should support real-time backup, and recordings must be kept for at least 30 days. For specially controlled medicines, recordings must be kept for at least 90 days.

7.Backup power supply. A dual power supply system or backup generator should be installed. The generator must at least support emergency lighting in storage areas and ensure normal operation of cold storage equipment, environmental monitoring systems, computer control rooms, and server centers.

8. Other required equipment. Any other equipment required by laws and regulations must also be provided.

Enterprises that handle refrigerated or frozen biological products or traditional Chinese medicine slices must meet items (4) to (7) above, and are encouraged to also meet the other equipment requirements listed in this article.

Article 14

Enterprises shall select enclosed pharmaceutical transport vehicles that are compatible with drug storage conditions and transportation scale, and shall comply with the following requirements:

1. For the transport of cold chain pharmaceuticals, professional cold chain transport equipment shall be provided in accordance with the quality management requirements for transported drugs and the scale of operation.

2. The technical performance of cold chain transport equipment shall meet the requirements of the applicable Specifications. Refrigerated vehicles shall be equipped with independent cooling and heating power supplies, on-board automatic temperature monitoring devices, and remote data transmission systems.

3. Transport vehicles shall be fitted with satellite positioning devices to enable real-time monitoring of vehicle transport conditions.

Article 15

Enterprises shall conduct validation of cold storage facilities, cold chain transport equipment, and automatic temperature and humidity monitoring systems prior to use, periodically, or after periods of non-use exceeding the specified time limits. They shall regularly calibrate measuring

instruments and temperature and humidity monitoring equipment, or have them verified by qualified third-party institutions, in accordance with the requirements of the applicable Specifications and relevant annexes.

Validation plans, reports, and data shall be scientifically sound and reliable. Original validation records, as well as on-site photographs or videos of validation activities, shall be retained in accordance with the prescribed requirements.

Article 16

Enterprises shall establish a computer-based information management system covering the entire pharmaceutical distribution process. Software systems, including operating systems, databases, network security, and application security management systems, shall be compatible with the scale of modern logistics operations and meet the requirements of logistics operations, quality management, traceability management, and information security.

The equipment and facilities used for data entry, modification, and storage shall ensure that all records are authentic, accurate, secure, and traceable.

Article 17

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, transportation management system, automatic temperature and humidity monitoring system, and pharmaceutical traceability system. The specific requirements are as follows:

1. The Enterprise Resource Planning (ERP) system shall cover the entire process of pharmaceutical business operations. The equipment and facilities used for data entry, modification, and storage shall ensure that all records are authentic, accurate, secure, and traceable.

2. The Warehouse Management System (WMS) shall be integrated in real time and accurately with the ERP system, equipment control system, and transportation management system. It shall enable full-process quality management and control of warehousing and logistics activities, including inbound, outbound, storage, maintenance, returns, inventory counting, and transportation of pharmaceuticals. It shall also provide full-process tracking and query functions for goods.

3. The equipment control system shall enable automatic and continuous logistics transfer across all warehouse operation processes. Its subsystems, facilities, and equipment shall be connected in real time with the warehouse management system.

4. The transportation management system shall have functions for tracking, recording, and scheduling pharmaceutical transport plans, product varieties, quantities, batch numbers, transport tools, personnel, dispatch times, arrival times, in-transit transport routes, receipt confirmation, and temperatures of cold-chain pharmaceuticals. Where transportation is outsourced, the consignor's transportation management system shall be interconnected in real time with the contractor's system, enabling full-process tracking, recording, and scheduling of pharmaceutical transport.

5. The automatic temperature and humidity monitoring system shall carry out real-time monitoring and recording of warehouse temperature and humidity, as well as the temperature of refrigerated and frozen pharmaceuticals during transport.

6. The pharmaceutical traceability system shall ensure traceability across all packaging levels, enabling verification and correlation of pharmaceutical products. It shall allow access to basic information of sold pharmaceuticals and shipment data from upstream enterprises, and transmit shipment data to downstream enterprises, ensuring that traceability data is authentic, accurate, complete, tamper-proof, and traceable.

Article 18

Prior to putting the pharmaceutical modern logistics system into operation, enterprises shall conduct trial operations on the information management system as well as on the compatibility between warehousing and logistics equipment and the enterprise's pharmaceutical modern logistics application, to ensure that data are authentic, accurate, secure, and traceable. Where the system has been suspended for more than six months, it shall undergo re-trial operation before being put back into service.

Article 19

Enterprises shall be equipped with computer hardware systems and network environments commensurate with the scale of pharmaceutical modern logistics, so as to ensure the continuous, stable operation of the system and the integrity and security of data. Data management of pharmaceutical modern logistics activities shall comply with the *Requirements for Pharmaceutical Record and Data Management (Trial)* (NMPA Announcement No. 74 of 2020). Data shall be backed up daily and stored and managed through secure and reliable means (including off-site servers, multi-machine hot standby, or cloud storage). Video surveillance image data shall be retained in accordance with Article 13 of these Guidelines. Other system data records shall be retained for at least five years, and not less than one year after the expiry date of the relevant medicinal products. For specially controlled medicinal products, applicable national provisions shall prevail.

Article 20

In addition to meeting the requirements on quality management, storage and transportation, information management systems, and relevant personnel applicable to wholesale enterprises, third-party logistics enterprises shall also comply with Articles 21 to 26 of these Guidelines.

Third-party logistics enterprises shall, on the basis of compliance with the *GMP*, carry out modern pharmaceutical storage and transportation activities. They shall perform their obligations in accordance with entrusted agreements and bear corresponding legal liability.

Article 21

Third-party logistics enterprises shall be equipped with at least two logistics management personnel and two computer management personnel. Personnel qualification requirements shall comply with Article 9 of these Guidelines.

Article 22

Third-party logistics enterprises shall possess storage conditions commensurate with the scale of pharmaceutical logistics. The total floor area of the pharmaceutical storage operation zone shall, in principle, not be less than the national general warehouse standard (10,000 square meters or a total volume of not less than 60,000 cubic meters).

Among these, the finished-product storage area shall be equipped with an automated high-bay warehouse or automated stereoscopic warehouse, with a capacity of not less than 25,000 cubic meters in principle. The loose-picking storage area shall be equipped with a picking system comprising not fewer than 3,500 storage locations.

Where cold-chain pharmaceutical logistics services for refrigerated or frozen medicines are carried out, at least two independent cold storage facilities shall be provided, with a total volume of not less than 500 cubic meters in principle. For medicines requiring special storage temperatures, warehouses and facilities shall also be provided in line with the storage requirements and operational scale of the relevant products.

Enterprises entrusted with vaccine storage and distribution shall establish no fewer than two independent vaccine cold storage facilities and ensure that vaccine cold storage facilities with non-combinable temperature zones are operated on a one-in-use, one-in-reserve basis.

Article 23

Third-party logistics enterprises shall be equipped with enclosed cargo transport vehicles. For the transportation of non-refrigerated or non-frozen medicines, the number of vehicles shall be no fewer than ten. For the transportation of refrigerated or frozen medicines, refrigerated

vehicles and onboard refrigeration equipment shall be provided, including no fewer than two refrigerated vehicles. Cold-chain transport equipment shall have automatic temperature control and display functions.

Where a third-party logistics enterprise entrusted with transportation needs to further subcontract transportation, it shall obtain the consent of the entrusting party and, in accordance with the *GMP Requirements*, conduct due diligence on the subcontracted carrier. The enterprise shall ensure full-process quality monitoring and effective traceability throughout transportation.

Article 24

Third-party logistics enterprises shall establish an information exchange platform to support the exchange of logistics operation data with the entrusting party. Such platform shall ensure the effective transmission of operational instructions from the entrusting party throughout the entire process, including receipt, inspection, warehousing, storage, maintenance, outbound handling, transportation, and returns of pharmaceuticals (the storage and transportation activities of the entrusted party shall comply with the operational instructions of the entrusting party's information system).

The platform shall enable full-process quality management of entrusted pharmaceutical storage and transportation and provide end-to-end cargo inquiry and traceability functions. It shall be capable of complete, timely, and accurate collection, recording, and retrieval of relevant data, ensuring that data records of different entrusting parties are kept separate and are not subject to interference or confusion, thereby enabling effective traceability of pharmaceutical information.

Third-party logistics enterprises shall, upon onboarding new entrusted business and during annual internal quality audits, conduct functional validation of the information exchange platform to ensure continuous, smooth, and effective connectivity of information between the entrusting and entrusted parties.

Article 25

Third-party logistics enterprises shall establish management systems for entrusted pharmaceutical storage and transportation, for instruction and information exchange with the entrusting party, and for the auditing of entrusting parties. Quality management records shall include, *inter alia*, records of receipt instructions and dispatch instructions issued by the entrusting party.

Article 26

Third-party logistics enterprises shall enter into contracts and quality assurance agreements with entrusting parties, covering the scope of entrusted pharmaceutical storage (and/or transportation), addresses, term of entrustment, record and data management, document management, quality responsibilities, traceability responsibilities, liabilities for breach, reporting of major issues, and evaluation requirements. Such agreements shall clearly define quality responsibilities as well as the respective rights and obligations of both parties.

Article 27

In carrying out pharmaceutical transportation activities, enterprises shall establish contingency plans and ensure appropriate handling under emergency conditions, so as to guarantee that pharmaceuticals transported comply with the requirements of the *GMP*.

Article 28

Marketing authorization holders, pharmaceutical manufacturers, and pharmaceutical distributors entrusting the transportation of pharmaceuticals shall assess the entrusted party's quality assurance capability and risk management capability, enter into entrusted agreements specifying pharmaceutical quality responsibilities, operating procedures, and other relevant matters, and exercise supervision over the entrusted party.

Third-party logistics enterprises shall assess their own capacity to undertake entrusted transportation activities, and the number of entrusting parties accepted shall be commensurate with their actual transportation capacity.

Article 29

An automated warehouse refers to a system that enables the automatic storage and retrieval of materials through automated and intelligent mechanical facilities (including high-rise shelving systems, automated storage and retrieval systems, load-handling robots, automatic sorting systems, intelligent single-item picking robots, automated inbound and outbound conveying systems, and related ancillary equipment), as well as computer-based management and control systems.

Multi-server hot standby refers to the use of two or more servers that back up each other and jointly provide the same service. When one server fails, other servers assume its functions, thereby ensuring continuous system service without manual intervention.

Validation of systems after exceeding downtime thresholds refers to the requirement that, where a temperature and humidity automatic monitoring system or cold storage facility has been out of service for more than six months, or where cold-chain transport equipment has

been out of service for more than three months, validation shall be conducted prior to reactivation.

Cold-chain transport equipment includes, but is not limited to, refrigerated trucks, refrigerated containers, insulated boxes, railway cold-chain wagons, air cargo refrigerated holds, and maritime or inland waterway refrigerated holds.

Article 30

Pharmaceutical regulatory authorities of provinces, autonomous regions, and municipalities directly under the Central Government may formulate specific standards and implementation rules for pharmaceutical modern logistics within their respective jurisdictions, in accordance with these Guidelines.

Article 31

These Guidelines shall enter into force on the date of their issuance.