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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 30335-2023

Specification for logistics service of medicinal product

药品物流服务规范

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Standardization Administration of the PRC

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. This document replaces GB/T 30335-2013 "Pharmaceutical Logistics Service Specifications". Compared with GB/T 30335-2013, except for structural adjustment and In addition to editorial changes, the main technical changes are as follows:

a) Added scope of inapplicability (see Chapter 1);

b) Delete the definition of pharmaceutical logistics (see

3.1 of the.2013 version);

c) Changed the facility and equipment requirements (see 4.5,

4.2 of the.2013 version), deleted specially managed drugs and national special management requirements Logistics service requirements for pharmaceuticals (see

4.3 of the.2013 version), management system requirements (see 4.1), and operational process requirements (see 4.2), emergency plan requirements (see 4.3);

d) Added personnel and training requirements (see Chapter 5);

e) Added facility and equipment requirements (see Chapter 6);

f) Added information system requirements (see Chapter 7);

g) The review requirements for inbound and outbound warehouses (see 8.1.1,

5.1.1 of the.2013 edition) and the preparation requirements for inbound and outbound warehouses (see 8.1.2,.2013 edition of 5.1.2), added requirements for additional materials entering and exiting the warehouse (see 8.1.3);

h) Changed the requirements for acceptance (see 8.2.3,

1 Scope

China's national specification for pharmaceutical logistics services, and the current edition of GB/T 30335, replacing the 2013 edition. It specifies the basic requirements for pharmaceutical logistics services together with the requirements for personnel and training, facilities and equipment, information systems, warehousing, transport and distribution, loading, unloading and handling, handover, value-added services, information management, risk management, complaint handling, and service evaluation and improvement. It applies to pharmaceutical logistics services and management activities, and it explicitly does not apply to logistics inside a hospital. Pharmaceutical logistics is distinguished from ordinary distribution by the fact that the product cannot be inspected on arrival for the property that matters. A carton of medicine that has spent six hours above its permitted temperature looks exactly like one that has not, and the harm - loss of potency, degradation to a different compound - is invisible until a patient does not respond to treatment. Everything in this document follows from that: the condition of the goods has to be assured by controlling and recording the process, because it cannot be verified at the end of it. Hence the temperature and humidity requirements throughout storage and transport, the cold chain requirements that reach back into GB/T 28842, the acceptance procedure with a designated area for goods awaiting inspection, the colour-coded status management that keeps accepted, quarantined and rejected stock physically separate, and the traceability requirements that let a specific batch be followed through every hand that touched it. The 2023 revision restructures the document around personnel, facilities, information systems and risk, adds requirements for the handling of drug safety incidents and for staff working in storage areas, and strengthens the acceptance and cold chain provisions. Issued and in force from 7 September 2023.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB 2894 Safety signs and guidelines for their use

GB 13495.1 Fire safety signs Part

GB/T 18354 Logistics terminology

GB/T 28842 Pharmaceutical cold chain logistics operation specifications Pharmacopoeia of the People's Republic of China

3 Terms and definitions

The terms and definitions defined in GB/T 18354 and GB/T 28842 apply to this document.

4 Basic requirements

4.1 A pharmaceutical logistics service management system should be formulated.

4.2 Operations such as drug warehousing, transportation and distribution, loading, unloading and handling, facilities and equipment, information systems, traceability, safety, emergency response, and internal audits should be formulated. process.

4.3 Emergency plans should be formulated for all aspects of drug storage, transportation and distribution, and emergency plan drills should be held regularly.

4.4 Organizational structure and position personnel suitable for pharmaceutical logistics services should be allocated.

4.5 There should be infrastructure, equipment tools and information systems suitable for pharmaceutical logistics services.

5 People and training

5.1 Pre-job and annual health examinations should be conducted for personnel who are directly exposed to drugs in pharmaceutical logistics services and management activities, and a health check-up system should be established. file. Those suffering from infectious diseases or other diseases that may contaminate medicines should not engage in work with direct contact with medicines.

5.2 An annual training plan should be formulated and training should be carried out as planned. Training content should include but not be limited to relevant laws and regulations, professional knowledge, positions Operating procedures, safety protection, emergency drills, etc.

5.3 Training records should be kept and training related situations should be evaluated.