

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



山東新華製藥股份有限公司

Shandong Xinhua Pharmaceutical Company Limited

(a joint stock company established in the People's Republic of China with limited liability)

(Stock Code: 00719)

OVERSEAS REGULATORY ANNOUNCEMENT

This overseas regulatory announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Shandong Xinhua Pharmaceutical Company Limited (the “**Company**”) will publish the “Announcement on having obtained the Drug Registration Certificate and Other Relevant Information” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 1 November 2025. The English translation of the relevant document is hereby included for reference. If there is any inconsistency between the English version and the Chinese version, the Chinese version shall prevail.

By Order of the Board

Shandong Xinhua Pharmaceutical Company Limited

He Tongqing

Chairman

31 October 2025, Zibo, the People's Republic of China

As at the date of this announcement, the board of directors of the Company comprises:

Executive Directors:

Mr. He Tongqing (*Chairman*)

Mr. Xu Wenhui

Mr. Hou Ning

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Ling Peixue

Ms. Cheung Ching Ching, Daisy

Non-executive Directors:

Mr. Xu Lie

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited**Announcement on having obtained the Drug Registration Certificate and Other Relevant Information**

The Company and its board of directors confirm that the contents of this announcement are true, accurate and complete without any false information, misleading statements or material omissions.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as “**Xinhua Pharmaceutical**” or the “**Company**”) has recently received the *Drug Registration Certificate* (藥品註冊證書) in connection with its Alendronate Sodium Oral Solution (hereinafter referred to as, the “**Product**”) issued under the authority of the National Medical Products Administration (國家藥品監督管理局). Relevant information is now announced as follows:

I. Basic information

Drug name:	Alendronate Sodium Oral Solution
Dosage form:	Oral solution
Specification:	75ml:70mg (calculated based on C ₄ H ₁₃ NO ₇ P ₂)
Drug classification:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Reception number:	CYHS2401018 、 CYHB2402066
Drug approval number:	National Medicine Zhunzi (国药准字) H20255791
Certificate number:	2025S03243
Approval Conclusion:	According to the <i>Drug Administration Law of the People’s Republic of China</i> and applicable regulations, upon review, the Product conforms with the applicable requirements for drug registration, the drug registration is approved, and the <i>Drug Registration Certificate</i> has been issued. The standard of quality, product instructions, labels as well as production processes concerning the Product shall be consummated in accordance with relevant documentation. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of drugs.

II. Other relevant information

In April 2024, Shandong Langnuo Pharmaceutical Co., Ltd. (hereinafter referred to as “**Shandong Langnuo**”) submitted application materials to the Center for Drug Evaluation of the National Medical Products

Administration (CDE) (药品审评中心) concerning the marketing of Alendronate Sodium Oral Solution and the application materials were accepted.

In May 2024, Xinhua Pharmaceutical and Shandong Langnuo signed a technology development contract. According to the contract, it was agreed that Xinhua Pharmaceutical shall own all the rights and benefits to the registration approval documents and related intellectual property, commercial rights and other rights to this Product after it has paid and settled all staged instalments of relevant transfer fees to Shandong Langnuo.

Pursuant to the *Rules Governing the Listing of Shares on Shenzhen Stock Exchange* (深圳证券交易所股票上市规则) and provisions of the articles of association of the Company (公司章程), the present transaction is not required to be submitted for the review and approval of the board of directors or shareholders' meeting of the Company. The present transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the *Measures for Administration of Material Assets Reorganization of Listed Companies* (上市公司重大资产重组管理办法).

In December 2024, Xinhua Pharmaceutical submitted the supplemental application materials for the change of the drug registration applicant to the CDE and the materials were accepted. In October 2025, the Company received the *Drug Registration Certificate*, and the review conclusion was to approve production of the Product.

Alendronate Sodium Oral Solution is suitable for the treatment of osteoporosis in postmenopausal women to prevent hip and spinal fractures (vertebral compression fractures) and osteoporosis in men to increase bone mass. According to relevant statistics, the sales of alendronate sodium across three major sales outlets, namely public hospitals, public primary medical institutions and retail pharmacies, amounted to approximately RMB 720 million in 2024.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical became the marketing license holder of the Product upon Alendronate Sodium Oral Solution having received the approval of the National Medical Products Administration in October 2025. The launch of the Product will help enrich the Company's product line and enhance the Company's overall competitive advantage.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement processes, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest sensibly and pay attention to investment risks.

By Order of the Board
**Shandong Xinhua Pharmaceutical
Company Limited**

31 October 2025