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 on having obtained the Notification of Approval of Supplementary Drug Application and Other Relevant Information*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 28 June 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

27 June 2025, Zibo, PRC

As at the date of this announcement, the Board comprises:

Executive Directors:

Mr. He Tongqing *(Chairman)*
Mr. Xu Wenhui
Mr. Hou Ning

Non-executive Directors:

Mr. Xu Lie
Mr. Zhang Chengyong

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Stock Code: 000756 Stock Short Name: Xinhua Pharmaceutical Announcement No.: 2025-39

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Having Obtained the Notification of Approval of Supplementary Drug Application 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 *Notification of Approval of Supplementary Drug Application* (药品补充申请批准通知书) issued under the authority of the National Medical Products Administration (药品审评中心) in connection with the approval of change of marketing licence holder of its Cobamamide Capsules (hereinafter referred to as, the "**Product**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Cobamamide Capsules
Dosage form:	Capsule
Specification:	0.5mg
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for change of marketing licence holder
Reception number:	CYHB2501161
Drug approval number:	National Medicine Zhunzi (国药准字) H20253418
Notification number:	2025B02823
Approval Conclusion:	According to the *Drug Administration Law of the People's Republic of China* and applicable regulations, upon review, the application concerning the Product complies with applicable requirements for drug registration and it is agreed that the change of the marketing licence holder in connection there with be approved in accordance with the relevant provisions of the *Measures for the Administration of Post-marketing Changes of Drugs (Trial)*.

II. Other relevant information

Xinhua Pharmaceutical and Beijing Baiya United Pharmaceutical Research Institute Company Limited (hereinafter referred to as "**Beijing Baiya**") signed a production technology and Marketing Authorization Holder (MAH) transfer contract in September 2024. According to the contract, Beijing Baiya shall make an one-off transfer of its license concerning the MAH status of Cobamamide Capsules and all related technical ownership rights (including production approval documentation, intellectual property rights relating to production technology, commercialization rights and related rights and benefits etc., including but not limited to from the aspects of production technology, sales and marketing, etc.) to Xinhua Pharmaceutical. The total technology transfer fee shall be payable by Xinhua Pharmaceutical to Beijing Baiya in accordance with staged

instalments as stipulated under the contract.

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 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 May 2025, Xinhua Pharmaceutical submitted application materials in connection with the change of marketing license holder of the Product to the National Medical Products Administration Drug Evaluation Center (CDE), and in June 2025, it received *Notification of Approval of Supplementary Drug Application* (药品补充申请批准通知书). The conclusion of the review evaluation is that the application for the transfer of holder of the Product complies with applicable requirements of post-listing administrative provisions, and the change of marketing licence holder of the Product was approved.

The Product is mainly applicable to treating conditions such as megaloblastic anemia, nutritional anemia, anemia during pregnancy, polyneuritis, radiculitis, trigeminal neuralgia, sciatica and nerve palsy. It can also be used as an adjuvant treatment for nutritional disorders and leukopenia caused by radiation and drugs.

The Product belongs to the Class A variety of "National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (2024)". According to relevant statistics, the sales of Cobamamide preparation in China's public medical institutions amount to approximately RMB 1.04 billion in 2024.

III. Impact on the Company and risk warning

Cobamamide capsules have been approved by the National Medical Products Administration in June 2025 and Xinhua Pharmaceutical became the marketing license holder of the Product. The launch of the Product will help enrich the Company's neurotrophic drugs 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

27 June 2025