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**") has published the "Announcement on Obtaining Approval Notice for Supplementary Drug Application and Other Relevant Information" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 3 September 2024. 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

3 September 2024, 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 Phramaceutical Announcement No.: 2024-40

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Obtaining Approval Notice for 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 Application concerning Drugs*（《药品补充申请批准通知书》）in connection with its pentoxifylline injections (hereinafter referred to as, the "**Product**") which was issued under the authority of the National Medical Products Administration. The change of marketing licence holder of the Product was approved. Relevant information is now announced as follows:

I. Basic information

Drug name:	Pentoxifylline injection
Dosage form:	Injection
Specification:	5ml : 0.1g
Drug classification:	Prescription drugs
Registration classification:	Chemical drugs category 3
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Supplementary application
Reception number:	CYHB2401223
Drug approval number:	National Medicine Zhunzi H20243881
Notification number.:	2024B03985
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 therewith 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

In August 2023, Xinhua Pharmaceutical and Suzhou Langke Biotechnology Co., Ltd. (hereinafter referred to as "**Suzhou Langke**") signed a technology transfer contract. According to the contract, Suzhou Langke shall make an one-off transfer of its license concerning the marketing and sales of pentoxifylline injection and all the rights and interests involved in relevant technology (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 Suzhou Langke 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 August 2024, 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 September 2024, it received notification concerning approval of the supplementary drug application. 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.

Pentoxifylline and its metabolites can improve hemorheological characteristics by reducing blood viscosity. In patients with chronic peripheral arterial diseases, it can increase the blood flow of affected microcirculation and increase the oxygenation of tissues. It is suitable for peripheral arterial diseases (intermittent claudication or resting pain) and inner ear circulatory disorders and belongs to the Class B variety of *National Drug List of Basic Medical Insurance, Work Injury Insurance and Maternity Insurance* (2023) (《国家基本医疗保险、工伤保险和生育保险药品目录(2023年)》). According to relevant data, the sales volume of pentoxifylline in city public hospitals in China reached RMB970 million in 2023, representing an increase of 11.98% from 2022, of which the sales volume in injection form amounted to RMB740 million.

III. Impact on the Company and risk warning

Pentoxifylline injection was approved by the National Medical Products Administration in September 2024, and Xinhua Pharmaceutical became the marketing license holder of the Product. The inclusion of marketing of this Product enriches the Company's product line and enhance its core competitiveness.

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

3 September 2024