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 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 13 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

13 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.: 2024-41

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 Application concerning Drugs*（《药品补充申请批准通知书》）issued by the National Medical Products Administration which approved the supplementary application for the transfer of holder of marketing authorisation in relation to the diazepam tablets (hereinafter referred to as, the "**Product**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Diazepam tablets
Dosage form:	Tablet
Specification:	2.5mg, 5mg
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Change of marketing authorization holder
Reception number:	CYHB2401253、CYHB2401252
Drug approval number:	National Medicine Zhunzi H22020354、National Medicine Zhunzi H22020355
Notification number.:	2024B04134、2024B04136
Review conclusion:	In accordance with *the Drug Administration Law of the People's Republic of China* and applicable regulations, upon review, the application in connection with the Product conforms with applicable requirements for drug registration and the change of the holder of marketing authorisation 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 February 2023, Xinhua Pharmaceutical and Jilin Xianfeng Technology Pharmaceutical Co., Ltd. (hereinafter referred to as "**Jilin Xianfeng**") entered into a technology transfer contract which stipulates that Jilin Xianfeng shall make an one-off transfer of its license concerning the marketing and sales of diazepam tablets and all the rights and interests involved in relevant technology (including production approval documentation, intellectual property rights relating to production technology, commercialisation 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 Jilin Xianfeng 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 holder of marketing authorisation concerning the Product to the National Medical Products Administration Drug Evaluation Center (CDE). In September 2024, Xinhua Pharmaceutical received notification concerning approval of the supplementary application. The conclusion of the review evaluation is that the application for the transfer of holder of marketing authorisation of the Product complies with applicable requirements of post-marketing administrative provisions, and the change of holder of marketing authorisation concerning the Product was approved.

Diazepam tablet is a long-acting benzodiazepine central nervous system depressant. Its mechanism of action mainly involves strengthening the inhibitory neurotransmitter γ -aminobutyric acid (GABA) in the brain. It is mainly used for anxiety relief, sedation and hypnosis, anti-epilepsy and anticonvulsant, relieving reflex muscle spasm caused by inflammation, treating panic disorder, muscle tension headache, familial, senile and idiopathic tremor, and can also be used for administration before anesthesia. According to relevant data, sales volume of Diazepam preparation in city public hospitals in China amounted to RMB50.65 million in 2023.

III. Impact on the Company and risk warning

Diazepam tablets (2.5mg, 5mg) were approved by National Medical Products Administration in September 2024, and Xinhua Pharmaceutical became the holder of marketing authorisation concerning the Product. The marketing of the Product is conducive to enriching the series of narcotic drugs of the Company and enhancing its comprehensive 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

13 September 2024