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 pregabalin capsules having obtained the drug registration certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 19 June 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

19 June 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 Annoucement No.: 2024-32

Shandong Xinhua Pharmaceutical Company Limited
Announcement on pregabalin capsules having obtained the drug registration certificate

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 (药品注册证书) for its pregabalin capsules (75mg,150mg) (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

Drug name:	Pregabalin capsules
Dosage form:	Capsules
Specifications:	150mg,75mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2200879、CYHS2200880
Drug approval number:	Guoyaozhunzi H20243976、Guoyaozhunzi H20243977
Certificate number:	2024S01142、2024S01143
Review conclusion:	In accordance with the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and relevant regulation, upon review, the Product conforms to the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labelling, as well as production process 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 June 2022, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning marketing of pregabalin capsules (150mg, 75mg) for domestic production and the application materials were accepted. In June 2024, Xinhua Pharmaceutical obtained the Drug Registration Certificate (药品注册证书) and the review conclusion was that: following review, the Product complied with applicable drug registration requirements, registration is approved and the Drug Registration Certificate is to be issued.

Pregabalin capsules are used to treat post-herpetic neuralgia and fibromyalgia. Pregabalin capsules belongs to category B variety of the "National Essential Medicines List" and "National Basic Medical Insurance, Work

Injury Insurance and Maternity Insurance Drug Catalog (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, in 2023, the sales of pregabalin capsules in capsules form in urban public hospitals in China reached RMB 391 million.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's pregabalin capsules (150mg, 75mg) has obtained the Drug Registration Certificate in June 2024, which is beneficial to the Company in terms of enriching its product line and enhancing the market competitiveness of the Product.

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
19 June 2024