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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 Pregabalin oral solution having obtained drug registration certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 24 April 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*

23 April 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

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 Pregabalin oral solution having obtained 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 Pregabalin oral solution (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 oral solution
Dosage form:	Oral solution
Specifications:	473ml: 9.46g
Drug category:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2302592
Drug approval number:	National Medicine Zhunzi (国药准字) H20253926
Certificate number:	2025S01076
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 with 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 September 2023, 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 oral solution and the application materials were accepted. In April 2025, Xinhua Pharmaceutical obtained the Drug Registration Certificate ( 药品注册证书 ), and the review conclusion was that it shall be approved for registration.

Pregabalin is used for the additional treatment of postherpetic neuralgia, fibromyalgia and partial seizures in

adults. Pregabalin oral solution belongs to the Class B variety of “National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (2024)”. According to relevant statistics, sales of Pregabalin oral solution in China’s public medical institutions amounted to RMB 624 million in 2023.

### **III. Impact on the Company and risk warning**

The obtaining by Xinhua Pharmaceutical of the drug registration certification for its Pregabalin oral solution in April 2025 will further enrich the Company's product structure and enhance its market 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**  
23 April 2025