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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 Lidocaine and Prilocaine Cream having obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 26 November 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*

25 November 2025 Zibo, the People's Republic of China

As at the date of this announcement, the board of directors of the Company 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 Lidocaine and Prilocaine Cream 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) in connection with its Lidocaine and Prilocaine Cream (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:	Lidocaine and Prilocaine Cream
Dosage form:	Cream
Specifications:	30g, Lidocaine 750mg and Prilocaine 750mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2400440
Drug approval number:	National Medicine Zhunzi (国药准字) H20255987
Notification number:	2025S03457
Review conclusion:	In accordance with the <i>Pharmaceutical Administration Law of the People's Republic of China</i> (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, labels 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 February 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Lidocaine and Prilocaine Cream and the application materials were accepted. In November 2025, Xinhua Pharmaceutical obtained the Drug Registration Certificate, and the review conclusion was that the Product shall be approved for registration.

Lidocaine and Prilocaine Cream is a preparation combination of Lidocaine and Prilocaine, used for local skin

anesthesia in the following situations: 1. Needle puncture, for example for use in catheter insertion or blood collection; 2. Superficial surgical operations, for example to apply to genital mucosa before superficial surgery or infiltration anesthesia; or leg ulcer cleaning/ debridement.

According to relevant statistics, the sales of Lidocaine and Prilocaine Cream in China's public medical institutions amounted to approximately RMB 615 million in 2024.

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

Xinhua Pharmaceutical's obtaining of *Drug Registration Certificate* in connection with its Lidocaine and Prilocaine Cream in November 2025 will be conducive to enriching the variety of digestive system drugs and enhancing the overall competitiveness of the Company.

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**  
25 November 2025