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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 Ursodeoxycholic Acid Capsules of subsidiary having obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 17 September 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*

16 September 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 Ursodeoxycholic Acid Capsules of subsidiary 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 Zibo Xincat Pharmaceutical Company Limited (hereinafter referred to as “**Xincat Pharmaceutical**”), a wholly-owned subsidiary of the Company, has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Ursodeoxycholic Acid Capsules (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:	Ursodeoxycholic Acid Capsules
Dosage form:	Capsule
Specifications:	250mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2400384
Drug approval number:	National Medicine Zhunzi (国药准字) H20255344
Notification number:	2025S02741
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, 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 January 2024, Xincat 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 Ursodeoxycholic Acid Capsules and the application materials were accepted. In September 2025, Xincat Pharmaceutical obtained the *Drug*

*Registration Certificate*, and the review conclusion was that the Product shall be approved for registration.

The Product is indicated for the treatment of gallbladder cholesterol stones (which must be X-ray-translucent and have normal gallbladder contraction function); cholestatic liver diseases (such as primary biliary cirrhosis); and bile reflux gastritis.

The Product is listed in the “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2024)” as a Category A product. According to relevant statistics, the sales of Ursodeoxycholic Acid Capsules in China’s public medical institutions amounted to approximately RMB 2.155 billion in 2024.

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

The obtaining of approval by Xincat Pharmaceutical in September 2025 in connection with its application for the Ursodeoxycholic Acid Capsules is conducive to enriching the variety of digestive system drugs for the Company and enhancing the Company's comprehensive 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**

16 September 2025