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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 Finasteride Tablets of Subsidiary Having Obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 6 August 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*

5 August 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 Finasteride Tablets 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 the “**Xincat Pharmaceutical**”), a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited, has recently received the *Drug Registration Certificate* (药品注册证书) for its Finasteride tablets (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:	Finasteride tablets
Dosage form:	Tablet
Specifications:	5mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2400153
Drug approval number:	National Medicine Zhunzi (国药准字) H20255064
Notification number:	2025S02419
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 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 Finasteride tablets and the application materials were accepted. In August 2025, Xincat Pharmaceutical obtained the *Drug Registration*

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

Finasteride tablets are indicated for the treatment and control of benign prostatic hyperplasia (BPH) and the prevention of urinary system events; reducing the risks of acute urinary retention and reducing the risks of requiring transurethral resection of the prostate (TURP) or prostatectomy. Finasteride tablets can shrink an enlarged prostate, improve urine flow and alleviate symptoms related to benign prostatic hyperplasia.

Finasteride tablets belong to the Class B variety of “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)”. According to relevant statistics, the sales of Finasteride tablets in China’s public medical institutions amounted to approximately RMB 1.45 billion in 2024.

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

The obtaining of the *Drug Registration Certificate* in connection with Finasteride tablets by Xincat Pharmaceutical in August 2025 is conducive to enriching the Company’s product range in exploring new market segments.

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**  
5 August 2025