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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 Phenobarbital Tablets having passed the generics consistency evaluation” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 19 May 2026. 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

18 May 2026 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. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited**Announcement on Phenobarbital Tablets having passed the generics consistency evaluation**

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 *Notice of Approval of Supplementary Drug Application* issued under the approval of the National Medical Products Administration in relation to its Phenobarbital Tablets (hereinafter referred to as the “**Product**”) having passed the “Consistency of Quality and Efficacy Evaluation for Generic Drugs” (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug name:	Phenobarbital Tablets
Dosage form:	Tablets
Specifications:	30mg
Drug category:	Prescription drugs
Registered classification:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Case number:	CYHB2550202
Drug approval number:	National Medicine Zhunzi (国药准字) H37020639
Notification number:	2026B02879
Review conclusion:	This Product passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs

II. Other relevant information

In May 2025, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) in connection with the consistency of quality and efficacy evaluation for generic drug, Phenobarbital Tablets, and the application was accepted. In May 2026, we Supplemental Drug Application Approval Notice (药品补充申请批准通知书) was granted with the conclusion that the Product had passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs.

The Product is mainly used for the treatment of anxiety, insomnia (for patients with short sleep duration and early awakening), epilepsy, and is a drug for the the treatment of [grand mal seizures and partial seizures].

The Product is listed in the “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)” as a Category A product. According to relevant statistics, the sales of Phenobarbital Tablets in China’s public medical institutions amounted to approximately RMB220 million in 2025.

III. Impact on the Company and risk warning

The Phenobarbital Tablets (30mg) of Xinhua Pharmaceutical having passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs in May 2026 is conducive to improving 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**
18 May 2026