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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 Sevelamer Carbonate for Suspension having obtained Drug Registration Certificate*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 2 June 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

1 June 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

Non-executive Directors:

Mr. Zhang Chengyong

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Shandong Xinhua Pharmaceutical Company Limited
Announcement on obtaining the Drug Registration Certificate for Sevelamer Carbonate for Suspension

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, "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Sevelamer Carbonate for Suspension (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:	Sevelamer Carbonate for Suspension
Dosage form:	Oral Suspension
Specifications:	0.8g;2.4g
Drug category:	Prescription drugs
Registered classification:	Class 3 Chemical Drug
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2404033, CYHS2404034
Drug approval number:	National Medicine Zhunzi (国药准字) H20264551, H20264552
Certification number:	2026S01792, 2026S01793
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 regulations, upon review, the Product conforms with the applicable requirements of drug registration, the drug registration is approved, and the Drug Registration Certificate has been issued. The standard of quality, product instructions, labels as well as production processes concerning the Product shall comply 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 November 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation(CDE) (药品审评中心) of the National Medical Products Administration concerning the marketing of Sevelamer Carbonate for Suspension and the application materials were accepted. Xinhua Pharmaceutical obtained the Drug Registration Certificate recently, and the review conclusion was that the Product shall be approved for registration.

This Product is used to control hyperphosphatemia in adult patients with chronic kidney disease (CKD) who are undergoing dialysis treatment. It is also used to control hyperphosphatemia in adult patients with chronic kidney disease who have serum phosphorus levels of ≥ 1.78 mmol/L but have not undergone dialysis.

The Product is listed in the "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)" as a Category B product. According to relevant statistics, the sales of Sevelamer-related preparations in China's public medical institutions amounted to approximately RMB750 million in 2025.

III. Impact on the Company and risk warning

The obtaining of *Drug Registration Certificate* in connection with Sevelamer Carbonate for Suspension by Xinhua Pharmaceutical recently will enrich antiviral drug product series for the Company and enhance 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
1 June 2026