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 Epinephrine Hydrochloride Injection having passed generics consistency evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 28 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

27 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

Non-executive Directors:

Mr. Xu Lie
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 Epinephrine Hydrochloride Injection having passed 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 *Notification of Approval of Supplementary Drug Application* issued under the approval of the National Medical Products Administration in relation to its Epinephrine Hydrochloride Injection (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:	Epinephrine Hydrochloride Injection
Dosage form:	Injection
Specifications:	1ml: 1mg (calculated based on $C_9H_{13}NO_3$)
Drug category:	Prescription drugs
Registered classification:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHB2450157
Drug approval number:	National Medicine Zhunzi (国药准字) H37020374
Notification number:	2025B05700
Review conclusion:	The Product passed the Consistency of Quality and Efficacy Evaluation for Generic 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) in connection with the consistency of quality and efficacy evaluation of the generic drug, Epinephrine Hydrochloride Injection, and the application was accepted. In November 2025, the 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 suitable for treating severe dyspnea caused by bronchospasm, can quickly relieve anaphylactic shock caused by medication or drugs, and can also be used to prolong the action time of infiltration anesthesia. It is the primary rescue drug for cardiopulmonary resuscitation in cases of cardiac arrest from various causes.

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 Epinephrine Hydrochloride Injection in China's public medical institutions amounted to approximately RMB 270 million in 2024.

III. Impact on the Company and risk warning

The Epinephrine Hydrochloride Injection of Xinhua Pharmaceutical having passed Consistency of Quality and Efficacy Evaluation for Generic Drugs in November 2025 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
27 November 2025