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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 Pentazocine injection having obtained the drug registration certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 12 March 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

11 March 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

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 Pentazocine injection having obtained the 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 Xinhua Pharmaceutical Company Limited (hereinafter referred to as “**Xinhua Pharmaceutical**” or the “**Company**”) has recently received the Drug Registration Certificate (药品注册证书) of Pentazocine injection (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:	Pentazocine injection
Dosage form:	Injection
Specifications:	1ml:30mg
Drug category:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2301361
Drug approval number:	Guoyaozhunzi H20253528
Certificate number:	2025S00610
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 to the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labelling 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 May 2023, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning marketing of Pentazocine injection for domestic production and the application materials were accepted. In March 2025, Xinhua Pharmaceutical obtained the Drug Registration Certificate (药品注册证书), and the review conclusion was that it shall be approved for registration.

Pentazocine is a partial agonist of opioid receptors. It exerts analgesic effects by inhibiting the conduction system of the central nervous system and is suitable for treatment of various types of chronic severe pain, such as cancerous pain, traumatic pain, and post-operative pain, can also be used for pre-operative or pre-anesthesia medication as an auxiliary medication for surgical anesthesia. According to relevant data, the sales of Pentazocine injection in China's public medical institutions amounted to RMB 915 million in 2023.

The raw materials for the Product are produced by Xinhua Pharmaceutical, following receipt of the relevant "Notification of Approval of Marketing Application for Chemical Substance Drugs" in November 2024. For details, please refer to the announcement released by the Company on 5 November 2024 on CNINFO <http://www.cninfo.com.cn>. (巨潮資訊網)

III. Impact on the Company and risk warning

Pentazocine injection (1ml:30mg) was approved in March 2025. The launch of this Product on the market has enriched the narcotics pharmaceutical product series of the Company and at the same time strengthened its advantages in ancillary production, enhancing the core competitiveness of the Company.

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**
11 March 2025