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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 Ibuprofen Suspension Drops Having Obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 23 May 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

22 May 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 Ibuprofen Suspension Drops 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 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) for Ibuprofen Suspension Drops (15ml:0.6g · 30ml:1.2g) (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:	Ibuprofen Suspension Drops
Dosage form:	Oral suspension
Specifications:	15ml:0.6g, 30ml:1.2g
Drug category:	Over the counter drug
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2303314, CYHS2303315
Drug approval number:	National Medicine Zhunzi (国药准字) H20254094, H20254095
Notification number:	2025S01279, 2025S01280
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 with the applicable requirements of drug registration, and the drug registration certificate has been issued. It is agreed that this product shall be managed as a (Class A) over-the-counter drug. 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 November 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 Ibuprofen suspension drops and the application materials were accepted. In May 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.

Ibuprofen inhibits the synthesis of prostaglandins and has antipyretic analgesic and anti-inflammatory effects. This Product is used for treating children with fever caused by common cold or influenza, as well as for providing mild to moderate pain relief for children, such as for treating headaches, joint pain, migraine, toothache, muscle pain, neuralgia and dysmenorrhea.

Ibuprofen suspension drops belongs to the Class B variety of “National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (2024)”. According to relevant statistical data, sales of Ibuprofen suspension drops in China’s public medical institutions amounted to approximately RMB 5.09 billion in 2023.

III. Impact on the Company and risk warning

The obtaining by Xinhua Pharmaceutical of the drug registration certification for its Ibuprofen suspension drops (15ml:0.6g,30ml:1.2g) in May 2025 will further enrich the Company's Ibuprofen preparation dosage variety, which is conducive to strengthening its supply and production advantages and enhancing the Company's overall 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**
22 May 2025