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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 will publish the “Announcement on Ibuprofen Arginine Having Obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 1 July 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

30 June 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 Ibuprofen Arginine Having Obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs**

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as “**Xinhua Pharmaceutical**” or 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.

The Company has recently received the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书) issued under the authority of the National Medical Products Administration in connection with its Ibuprofen Arginine (hereinafter referred to as the “**Product**”). Relevant information is now announced as follows:

I. Basic information

API name:	Ibuprofen Arginine
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for the Listing of Domestic Production of Chemical Raw Materials
Reception number:	CYHS2360825
Registration number:	Y20230001014
Notification number:	2025YS00509
Review conclusion:	According to the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and applicable regulation, upon review, the Product conforms with applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation.

II. Other relevant information

In November 2023, Xinhua Pharmaceutical submitted an application for the registration of Ibuprofen Arginine to the Center for Drug Evaluation of the National Medical Products Administration and such application was accepted. In June 2025, Xinhua Pharmaceutical obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

Ibuprofen Arginine is mainly used for treating toothache, dysmenorrhea, pain due to trauma (e.g. sports injuries), joint and ligament pain, back pain, headache, neuralgia, and fever due to influenza.

The Product is an antipyretic and analgesic non-steroidal anti-inflammatory drug of propionic acid, and its preparation belongs to the Class B variety of “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)”. According to relevant statistics, sales of Ibuprofen Arginine preparation in China’s public medical institutions amounted to approximately RMB 114 million in

2024.

III. Impact on the Company and risk warning

The obtaining by Xinhua Pharmaceutical of the *Notification of Approval of Marketing Application for Chemical Substance Drugs* in June 2025 will further enrich the Company's product line and enhance its core 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**

30 June 2025