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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**”) has published the “Announcement on ibuprofen sustained release capsules obtaining the drug registration certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 12 March 2024. 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

12 March 2024, 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
Mr. Cheung Ching Ching, Daisy

Shandong Xinhua Pharmaceutical Company Limited

Announcement on ibuprofen sustained release capsules obtaining 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 received the Drug Registration Certificate (药品注册证书) of ibuprofen sustained release capsules (hereinafter referred to as the “**Product**”) approved and issued by the National Medical Products Administration of the People’s Republic of China. Relevant information is now announced as follows:

I. Basic information

Drug name: Ibuprofen sustained release capsules

Dosage form: Capsules

Specifications: 0.3g

Drug category: Over the counter drug

Registered category: Class 4 chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application matter: Drug registration (Domestic production)

Approval number: CYHS2200983

Drug approval number: Guoyao Zhunzi (国药准字)H20243295

Notification number: 2024S00352

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 application regulation, upon review, the Product conforms to the applicable requirements for drug registration, and the drug registration certificate has been issued. Agree that this Product shall be administered as a Class A over-the-counter drug. The standard of quality, product instructions and labelling as well as the 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 June 2022, 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 sustained release capsules for domestic production and the application materials were accepted. In March 2024, Xinhua Pharmaceutical obtained the Drug Registration Certificate(药品注册证书), and the review conclusion was approved for production.

Ibuprofen is an over-the-counter antipyretic and analgesic drug, which is an effective PG synthase inhibitor with antipyretic, analgesic, and anti-inflammatory effects. It is mainly used to relieve mild to moderate pain such as headache, arthralgia, migraine, toothache, myalgia, neuralgia, dysmenorrhea, and also used for fever caused by common cold or influenza.

Ibuprofen belongs to Class A over-the-counter (OTC) drugs and category B variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2022)”(国家基本医疗保险、工伤保险和生育保险药品目录(2022年)).According to available data, the global sales of ibuprofen related formulations in 2023 were about 4.357 billion US dollars, and the sales of ibuprofen related formulations in Chinese public medical institutions in 2022 were about 1.338 billion yuan.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's ibuprofen sustained release capsules has obtained the Drug Registration Certificate in March 2024, further enriching the Company's ibuprofen products series,which is beneficial for the Company to provide new medication options for antipyretic and analgesic patients.

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**

12 March 2024