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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 an “*Announcement in relation to obtaining of the Notification of Approval of Supplementary Drug Application and Other Relevant Information*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 2 April 2026. The English translation of the relevant announcement 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 of directors of the Company
Shandong Xinhua Pharmaceutical Company Limited
He Tongqing
Chairman

1 April 2026, 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

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Non-executive Directors:

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement in relation to obtaining of the Notification of Approval of Supplementary Drug Application and Other Relevant Information

The Company and its board of directors confirm that the contents of this announcement are true, accurate and complete without any false information, misleading statement or material omission.

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* (药品补充申请批准通知书) issued under the authority of the National Medical Products Administration (药品审评中心) in connection with the approval of change of marketing licence holder of its Galculus Bovis and Metronidazole Capsules (hereinafter referred to as, the “**Product**”). Relevant information is now announced as follows:

I. Basic information

Drug name:	Galculus Bovis and Metronidazole Capsules
Dosage form:	Capsules
Specification:	Metronidazole 0.2g, Calculus Bovis Artifactus 5mg
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for change of marketing licence holder
Reception number:	CYHB2600473
Drug approval number:	National Medicine Zhunzi (国药准字) H22026771
Notification number:	2026B02018
Approval conclusion:	According to the <i>Drug Administration Law of the People’s Republic of China</i> and relevant regulations, upon review, the application concerning the Product complies with applicable requirements for drug registration and it is agreed that the change of the marketing licence holder in connection therewith be approved in accordance with the relevant provisions of the <i>Measures for the Administration of Post-marketing Changes of Drugs (Trial)</i> .

II. Other relevant information

In September 2023, Xinhua Pharmaceutical and Jilin Zhongsheng Pharmaceutical Company Limited (吉林省中晟制药有限公司) (hereinafter referred to as “**Zhongsheng Pharmaceutical**”) signed a production technology and holder transfer contract. According to the contract, Zhongsheng Pharmaceutical shall make a one-off transfer of all its *Marketing Authorization Holder* (MAH) rights (including, without limitation, formulation production approval and commercialization rights (including, but not limited to, those relating to product manufacturing, sales and marketing) to Xinhua Pharmaceutical. The total technology transfer fee shall

be payable by Xinhua Pharmaceutical to Zhongsheng Pharmaceutical in accordance with staged instalments as stipulated under the contract.

Pursuant to the Rules Governing the Listing of Shares on Shenzhen Stock Exchange (深圳证券交易所股票上市规则) and the articles of association of the Company (公司章程), the present transaction is not required to be submitted for the review and approval of the board of directors or shareholders' meeting of the Company. The present transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the *Measures for Administration of Material Assets Reorganization of Listed Companies* (上市公司重大资产重组管理办法).

In March 2026, Xinhua Pharmaceutical submitted application materials in connection with the change of *Marketing Authorization Holder* of the Product to the National Medical Products Administration Drug Evaluation Center (CDE), and recently, it received the *Notification of Approval of Supplementary Drug Application* (药品补充申请批准通知书). The conclusion of the review evaluation is that the application concerning the Product complies with applicable requirements for drug registration, and the change of *Marketing Authorization Holder* of the Product was approved.

The Product is suitable for acute wisdom tooth pericoronitis, local alveolar abscess, pulpitis, periapical periodontitis, etc.

According to relevant statistics, the sales of galculus bovis and metronidazole capsules in China's public medical institutions amounted to approximately RMB579 million in 2024.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical became the *Marketing Authorization Holder* of Galculus Bovis and Metronidazole Capsules following the obtaining of approval from the National Medical Products Administration recently. This shall be beneficial to enriching the Company's pharmaceutical formulation product line and enhances its comprehensive competitiveness.

The pharmaceutical sales business is susceptible changes in domestic pharmaceutical industry policies, tendering and procurement processes, changes in 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**

1 April 2026