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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 published the "Announcement on Aminophylline Tablets passing the Generics Drugs Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 15 April 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

14 April 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 Aminophylline Tablets passing the Generic Drugs Consistency Evaluation

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 *Notifaction of Approval of Supplementary Drug Application* (药品补充申请批准通知书) from the National Medical Products Administration in relation to the approval of Aminophylline Tablets (hereinafter referred to as the "**Product**"), having passed the "Consistency of Quality and Efficacy Evaluation for Generic Drugs" (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug name:	Aminophylline Tablets
Dosage form:	Tablets
Specifications:	0.1g (calculated as $C_2H_8N_2(C_7H_8N_4O_2)_2 \cdot 2H_2O$)
Drug category:	Prescription drugs
Registered classification:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Case number:	CYHB2450168
Drug approval number:	Guoyao Zhunzi (国药准字) H37020630
Certificate number:	2025B01572
Review conclusion:	The Product passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs.

II. Other relevant information

In March 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) in connection with consistency of quality and efficacy evaluation for the generic drug, Aminophylline Tablets, and the application was accepted. In April 2025, Xinhua Pharmaceutical received the "Notification of Approval of Supplementary Drug Application: (药品补充申请批准通知书), which concluded that the Product passed the consistency of quality and efficacy evaluation for generic drugs.

The Product is a complex salt of theophylline and ethylenediamine, and its pharmacological effect mainly comes from theophylline, which enhances its water solubility. The Product has a direct relaxation effect on

respiratory smooth muscles and is suitable for relieving wheezing symptoms such as asthmatic bronchitis, obstructive pulmonary emphysema, etc.. It can also be used for asthma caused by cardiogenic pulmonary edema.

Aminophylline tablets belong to the category A variety of the "National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (2023)" (国家基本医疗保险、工伤保险和生育保险药品目录(2023年)). According to relevant data, the sales of aminophylline in China's public medical institutions in 2023 reached approximately RMB651 million.

III. Impact on the Company and risk warning

The aminophylline API used in the production of the Product is produced by Xinhua Pharmaceutical. The passing of consistency evaluation of generics drug quality and efficiency concerning the Product is conducive to enhancing the market competitiveness of the Product.

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
14 April 2025