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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 Calcium Gluconate Injection Passing the Generics Consistency Evaluation” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 5 November 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

5 November 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
Ms. Cheung Ching Ching, Daisy

Shandong Xinhua Pharmaceutical Company Limited**Announcement on Calcium Gluconate Injection Passing the Generics 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 *Notication of Approval of Supplementary Drug Application* (药品补充申请批准通知书) from the National Medical Products Administration in connection with the approval of calcium gluconate injection (10ml:1g) (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:	Calcium gluconate injection
Dosage form:	Injection
Specifications:	10ml:1g(calculated based on $C_{12}H_{22}CaO_{14}$)
Drug category:	Prescription drugs
Registration category:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Approval number:	CYHB2350545
Original drug approval number:	Guoyao Zhunzi (《国药准字》) H37020733
Notification number:	2024B05037
Review conclusion:	Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In July 2023, 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 its generic drug, calcium gluconate injection (10ml:1g), and the application was accepted. In November 2024, the Company was issued a *Notication 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.

Calcium gluconate injection is clinically used to treat hand-foot weakness caused by calcium deficiency, acute hypocalcemia, alkalosis and hypoparathyroidism, allergic diseases, relief from magnesium poisoning, relief

from fluorosis and during cardiac resuscitation (such as hyperkalemia or hypocalcemia, or heart function abnormalities caused by calcium channel blockade).

The Product has been included in the “National Essential Drugs List (2018 edition)” (国家基本药物目录(2018版)) and belongs to the category A variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2024)”(《国家基本医疗保险、工伤保险和生育保险药品目录(2024年)》). According to relevant data, sales volume of Calcium gluconate injection in Chinese public medical institution is approximately RMB 360 million in 2023.

III. Impact on the Company and risk warning

The approval of Xinhua Pharmaceutical’s calcium gluconate injection (10ml:1g) in November 2024 having passed the evaluation of the quality and efficacy consistency of generic drugs is conducive to enhancing the Product’s market 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**

5 November 2024