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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 sodium bicarbonate injection having passed the generics consistency evaluation” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 29 May 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*

29 May, 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 sodium bicarbonate injection having passed 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 Notice of Approval of Supplementary Drug Application from the National Medical Products Administration (《药品补充申请批准通知书》) that its sodium bicarbonate injection (hereinafter referred to as the “**Product**”) has 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:

**1. Basic information**

|                                |   |
|--------------------------------|---|
| Drug name:                     | Sodium bicarbonate injection  |
| Dosage form:                   | Injection   |
| Specifications:                | 10ml:0.84g  |
| 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:               | CYHB2340012   |
| Original drug approval number: | Guoyao Zhunzi (《国药准字》)H20227054   |
| Notification number:           | 2024B02304  |
| Review conclusion:             | Passed the consistency of quality and efficacy evaluation for generic drugs |

**2. Other relevant information**

In March 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 drugs, sodium bicarbonate injection (10ml:0.84g), and the application was accepted. In May 2024, the Company was granted a Supplemental Drug Application Approval Notice (《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 company was the first manufacturer of sodium bicarbonate injection with 10ml:0.84g specification to pass the consistency evaluation.

Sodium bicarbonate injection is suitable for the treatment of metabolic acidosis and for alkalinizing urine. Intravenous infusion has a nonspecific therapeutic effect on certain drug poisoning.

Sodium bicarbonate injection belongs to the category A variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (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 volume of sodium bicarbonate in China’s urban public hospitals was about RMB 561 million in 2023, of which the sales volume of sodium bicarbonate injections was about RMB 497 million.

### **3. Impact on the Company and risk warning**

The passing of quality and efficacy consistency evaluation by Xinhua Pharmaceutical’s sodium bicarbonate injection (10ml: 0.84g) is conducive to enriching the product series of the Company and 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 rationally and pay attention to investment risks.

By Order of the Board  
**Shandong Xinhua Pharmaceutical Company  
Limited**

29 May 2024