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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 Rabeprazole Sodium Enteric-coated Tablets (20mg) Passing the Generics Consistency Evaluation" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 14 July 2023, the English version 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 July 2023, Zibo, PRC

As at the date of this announcement, the Board comprises:

Executive Directors:

Mr. He Tongqing (*Chairman*)

Mr. Xu Wenhui

Mr. Hou Ning

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Lo Wah Wai

Mr. Ling Peixue

Non-executive Directors:

Mr. Cong Kechun

Mr. Xu Lie

## Shandong Xinhua Pharmaceutical Company Limited

### Announcement on Rabeprazole Sodium Enteric-coated Tablets (20mg) Passing the Generics Consistency Evaluation

The Company and the 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 (《药品补充申请批准通知书》) from the *National Medical Products Administration* in relation to the approval of Rabeprazole Sodium Enteric-coated Tablets (雷贝拉唑钠肠溶片) (20mg) (hereinafter referred to as the "**Product**"), which has approved the addition of 20mg specifications and 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: Rabeprazole Sodium Enteric-coated Tablets

Dosage form: Tablets

Specifications: 20mg

Drug Category: Prescription Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Add specifications and apply for consistency evaluation of generic drug quality and efficacy

Acceptance Number: CYHB2250512

Original drug approval number: Guoyao Zhunzi (《国药准字》)H20237076

Notification number: 2023B03494

Approval Conclusion: The addition of 20mg specification and passed the consistency of quality and efficacy evaluation for generic drugs.

#### II. Other relevant information

In August 2022, Xinhua Pharmaceutical submitted registration materials to the *Center for Drug Evaluation of the State Drug Administration* (药品审评中心) to apply for “Consistency of Quality and Efficacy Evaluation for Generic Drugs” for the Product, the receipt of which was accepted. In July 2023, the Company received a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which approved that the addition of 20mg specification as well as the evaluation for consistency of quality and efficacy of the generic drug.

Rabeprazole sodium is a third-generation proton pump inhibitor used for the treatment of gastric ulcers, duodenal ulcers, anastomotic ulcers, reflux esophagitis, and Zollinger Ellison syndrome. It is also used to assist in eradicating *Helicobacter pylori* in patients with gastric or duodenal ulcers. Rabeprazole sodium enteric-coated tablets belongs to the category B variety of the “National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2021 Edition)” (《国家基本医疗保险、工伤保险和生育保险药品目录(2021年)》). According to relevant data, the sales of rabeprazole in urban public hospitals in China reached RMB 3.33 billion in 2022, of which the sales in oral dosage forms reached RMB 2.21 billion.

The 10mg version of Xinhua Pharmaceutical’s rabeprazole sodium enteric-coated tablets has passed the “Consistency of Quality and Efficacy Evaluation for Generic Drugs” in June 2023, and the above refers to the 20mg version of the generic drug. The active pharmaceutical ingredients (API) of the above two specifications of the rabeprazole sodium enteric-coated tablets that passed the evaluation were self-produced by Xinhua Pharmaceutical.

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

Xinhua Pharmaceutical's rabeprazole sodium enteric-coated tablets (specifications: 20mg) has passed the “Consistency of Quality and Efficacy Evaluation for Generic Drugs” in July 2023, which will be beneficial to enrich the product series, strengthen its production capability, and enhance the competitiveness of the product in the market.

The pharmaceutical sales business is susceptible to changes in policies which affects the domestic pharmaceutical industry, 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**

14 July 2023