

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



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**”) shall publish the “Announcement on New Specifications of Aspirin Enteric-coated Tablets passing the Generics Drugs Consistency Evaluation” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 29 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*

28 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

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Ling Peixue

Ms. Cheung Ching Ching, Daisy

Non-executive Directors:

Mr. Xu Lie

Mr. Zhang Chengyong

**Shandong Xinhua Pharmaceutical Company Limited**  
**Announcement on New Specifications of Aspirin Enteric-coated Tablets passing the Generics 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 *Notification of Approval of Supplementary Drug Application* (药品补充申请批准通知书) issued by the National Medical Products Administration in relation to the approval of Aspirin Enteric-coated Tablets (阿司匹林肠溶片) (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:	Aspirin Enteric-coated Tablets
Dosage form:	Tablets
Specifications:	100mg
Drug category:	Prescription drugs
Registered classification:	Chemical medicine
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Inclusion of 100mg specification and at the same time apply for Consistency of Quality and Efficacy Evaluation for Generic Drugs
Case number:	CYHB2450201
Drug approval number:	Guoyao Zhunzi (国药准字) H20258068
Certificate number:	2025B01839
Review conclusion:	After review, the supplementary application for the inclusion of the 100mg specification was approved for the Product, and the drug approval number was issued. The Product passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs.

**II. Other relevant information**

In March 2024, Shandong Xinhua Pharmaceutical Company Limited submitted registration 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 of the generic drug, Aspirin Enteric-coated Tablets together with the added specification, and the application was accepted. In May 2025, we were granted a “Notification of Approval of Supplementary Drug Application” (药品补充申请批准通知书), which

concluded that, after review, the supplementary application in connection with the inclusion of the 100mg specification of the Product was approved and that the drug approval number be issued. The Product also passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs.

Aspirin Enteric-coated Tablets are hematologic drugs, and are mainly used in clinical practice for: the treatment of unstable angina pectoris (part of standard treatment); acute myocardial infarction (part of standard treatment); the prevention of recurrence of myocardial infarction; use after arterial vascular or interventional surgeries (such as aortic coronary venous bypass surgery, percutaneous coronary intraluminal angioplasty); the prevention of transient ischemia attack (TIA) and prevention of cerebral infarction after early symptoms have occurred.

Aspirin Enteric-coated Tablets belong to the Class B variety under the “National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (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 statistical data, the sales of Aspirin Enteric-coated Tablets in China’s public medical institutions amount to approximately RMB 3.3 billion in 2023.

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

The Aspirin Enteric-coated Tablets (100mg) of Xinhua Pharmaceutical having passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs in April 2025 which will help enrich the Company’s product series and enhance 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**

28 April 2025