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 New Drug Specifications and Passing the Generics Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 10 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

10 July, 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. Cong Kechun

Mr. Xu Lie

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Lo Wah Wai

Mr. Ling Peixue

Shandong Xinhua Pharmaceutical Company Limited

Announcement on New Drug Specifications and 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》） issued by the National Medical Products Administration in relation to the approval of Dobutamine Hydrochloride Injection (盐酸多巴酚丁胺注射液) (hereinafter referred to as the "**Product**"), which 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:

I. Basic information

Drug Name: Dobutamine Hydrochloride Injection

Dosage form: Injection

Specifications: 5ml:100mg

Drug Category: Prescription Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Add 5ml:100mg Specification and Apply for Consistency of Quality and Efficacy Evaluation for Generic Drugs

Reception Number: CYHB2250052

Original drug approval number: Guoyao Zhunzi (《国药准字》) H37020712

Notification number:2023B03333

Approval Conclusion: After review, the supplementary application of 5ml:100mg was approved for this product, and the drug approval number was issued. This product passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In January 2022, Xinhua Pharmaceutical submitted registration materials for the consistency of quality and

efficacy evaluation for generic drugs of dobutamine hydrochloride injection (5ml:100mg) to the Center for Drug Evaluation of the State Drug Administration (the "**CDE**") (药品审评中心) and was accepted. In July 2023, we were granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that the Company had passed the consistency of quality and efficacy evaluation for generic drugs.

Dobutamine hydrochloride injection was first developed by LILLY Company in 1978 and applied for lauching in the United States (Trade name:DOBUTREX®). Manufacturers listed under ANDA include TEVA PARENTERAL, HOSPIRA, WATSON LABS, HIKMA PHARMS, and other companies. Subsequently, dobutamine hydrochloride injection was approved for launching in countries such as the European Union, Japan, and China.

Dobutamine hydrochloride injection is clinically used to heart failure caused by decreased myocardial contractility in organic heart disease, including low output syndrome after direct cardiac surgery,as a short-term supportive treatment .

According to the CDE official website, as of now, Xinhua Pharmaceutical is the second enterprise in China to pass the consistency evaluation of the Product. As a major emergency product in departments such as emergency, ICU, cardiology, cardiology, and pediatrics, dobutamine hydrochloride injection has been included in the National Basic Drug Catalog (2018 Edition) and the National Medical Insurance (2022 Edition) Class A Drug Catalog. It is also used to assist in eradicating Helicobacter pylori in patients with gastric or duodenal ulcers. According to relevant data statistics, the total sales of dobutamine hydrochloride injection in public medical institutions in China in 2022 exceeded RMB 532 million.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's dobutamine hydrochloride injection (5ml:100mg) has passed the consistency of quality and efficacy evaluation for generic drugs in July 2023, which will help further enhance the Product's market competitiveness.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement, 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

10 July 2023