

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 Co., Ltd. (the "**Company**") has published the "Announcement on acetamide obtaining notification of approval of marketing application for chemical substance drugs" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 16 March 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

16 March 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 acetamide obtaining notification of approval of marketing application for chemical substance drugs

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 Notification of Approval of Marketing Application for Chemical Substance Drugs (《化学原料药上市申请批准通知书》) of acetamide (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

Drug Name: acetamide

Dosage form: Active Pharmaceutical Ingredients

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Application for listing domestic production of chemical API

Reception Number: CYHS2060481

Registration Number: Y20200001357

Notification Number: 2023YS00090

Approval Conclusion: In accordance with the Drug Administration Law of the People's Republic of China, the Product conforms to the relevant requirements of drug registration after review, and registration application has been approved. The production techniques, quality standards and labelling shall be carried out as attached.

II. Other relevant information

In December 2020, Xinhua Pharmaceutical submitted to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for the registration of acetamide. In March 2023, Xinhua Pharmaceutical obtained Notification of Approval of Marketing Application for Chemical Substance Drugs 《化学原料药上市申请批准通知书》 and the review concluded that the application for registration of the Product was approved.

Acetamide is a newly developed raw material drug of Xinhua Pharmaceutical. Its preparation is acetamide injection. The acetamide injection of Xinhua Pharmaceutical is an exclusive variety in China. It is used for the special detoxification of fluoroacetamide, sodium fluoroacetate and glycofluoride poisoning using intramuscular injection. There are often incidents of poisoning by ingestion of fluoroacetamide, sodium fluoroacetate and glycine fluoride in China. Acetamide injection is a specific antidote and has a definite effect. Over the years, Xinhua Pharmaceutical has taken the initiative to assume social responsibility and ensure the effective reserve of acetamide injection.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical, as the exclusive applicant and approved enterprise of acetamide chemical raw materials, obtained the approval notice of listing application of chemical raw materials in March 2023, which is one of the important measures for the Company to strengthen and supplement the product chain, and is conducive to the Company to further play its supporting production advantages.

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**

16 March 2023