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 cefaclor capsules of wholly-owned subsidiary passing the generics consistency evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 10 April 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

10 April 2024, 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

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2024-18

Shandong Xinhua Pharmaceutical Company Limited

Announcement on cefaclor capsules of wholly-owned subsidiary passing 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 Zibo Xinda Pharmaceutical Company Limited (hereinafter referred to as "**Xinda Pharmaceutical**", a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as 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 cefaclor capsules (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: Cefaclor capsules

Dosage form: Capsules

Specifications: 0.25g (Calculated by $C_{15}H_{14}ClN_3O_4S$)

Drug category: Prescription drugs

Registered category: Chemicals

Applicant: Shandong Zibo Xinda Pharmaceutical Company Limited

Application matter: Consistency of Quality and Efficacy Evaluation for Generic Drugs

Approval number: CYHB2250649

Original drug approval number: Guoyao Zhunzi (《国药准字》)H10930008

Notification number: 2024B01534

Review conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In October 2022, Xinda Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning the consistency of quality and efficacy evaluation for generic drugs of cefaclor capsules and the application was accepted. In February 2024, Xinda Pharmaceutical was granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that Xinda Pharmaceutical passed the consistency of quality and efficacy evaluation for generic drugs.

Cefaclor was first developed by Eli Lilly in the United States. It is the second generation of oral cephalosporin, with broad-spectrum anti Gram positive and Gram negative effects bacteria. Its mechanism of action is the same as other cephalosporins, mainly by inhibiting the synthesis of cell walls to achieve bactericidal effects. It

is suitable for treating otitis media, lower respiratory tract infections (including pneumonia), upper respiratory tract infections (including pharyngitis and tonsillitis), urinary tract infections (including pyelonephritis and cystitis), skin and skin tissue infections, sinusitis, and gonococcal urethritis caused by sensitive strains.

Cefaclor Capsules belongs to the category B 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 of cefaclor in urban public hospitals in China reached RMB 941 million in 2022 in monetary terms.

III. Impact on the Company and risk warning

Xinda Pharmaceutical's cefaclor capsules have passed the consistency of quality and efficacy evaluation for generic drugs in February 2024, 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 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

10 April 2024