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 Drugs of Wholly-owned Subsidiary Passing the Generics Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 4 November 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

4 November 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.: 2024-57

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Drugs 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.

A wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited, Shandong Zibo Xincat Pharmaceutical Company Limited (hereinafter referred to as "**Xincat Pharmaceutical**"), 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 cefuroxime axetil dispersible tablets (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:	Cefuroxime axetil dispersible tablets
Dosage form:	Tablet
Specifications:	0.25g (calculated based on $C_{16}H_{16}N_4O_8S$)
Drug category:	Prescription drugs
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Approval number:	CYHB2350519
Original drug approval number:	Guoyao Zhunzi (《国药准字》) H20143270
Notification number:	2024B04986
Review conclusion:	In accordance with the provisions of the *Drug Administration Law of the People's Republic of China* (中华人民共和国药品管理法), *Opinions of the State Council on Reforming the Examination and Approval System of Drugs and Medical Devices (Guo Fa [2015] No.44)* (国务院关于改革药品医疗器械审评审批制度的意见)(国发〔2015〕44号) and the *Announcement on Relevant Matters Concerning the Evaluation of the Consistency of the Quality and Efficacy of Generic Drugs* (No.100, 2017) (关于仿制药质量和疗效一致性评价工作有关事项的公告) (2017年第100号), upon review, the Product has passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs.

II. Other relevant information

In July 2023, Xincat Pharmaceutical submitted 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 for the genric drug, cefuroxime axetil dispersible tablets, and the application was accepted. In November 2024, Xincat Pharmaceutical was granted the Notication of Approval of Supplementary Drug Application (药品补充申请批准通知书), which concluded that the Product passed the consistency of quality and efficacy evaluation for generic drugs.

Cefuroxime axetil belongs to the second generation cephalosporin antibiotics, serving as an oral prodrug of the bactericidal cephalosporin cefuroxime, resistant to most β -lactamases and effective against a wide range of gram-positive bacteria and gram-negative bacteria. Cefuroxime axetil is suitable for treating the following infectious diseases caused by sensitive bacteria: acute tonsillitis, pharyngitis and acute bacterial sinusitis; acute bacterial otitis media; acute attack of chronic bronchitis; uncomplicated skin and soft tissue infection; uncomplicated urinary tract infection; treatment of early Lyme disease (in adults and children over the age of 3 months); gonorrhea, acute gonococcal urethritis without complications and cervicitis.

The Product has been included in the "National Essential Drugs List (2018 edition) " (国家基本药物目录(2018)版) and belongs to the category A variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (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 data, sales volume of cefuroxime preparations in urban public hospitals in China was approximately RMB 1.593 billion in 2023.

III. Impact on the Company and risk warning

The passing of consistency evaluation of generic drug quality and efficacy in November 2024 concerning cefuroxime axetil dispersible tablets of Xincat Pharmaceutical, is conducive to further improving 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

4 November 2024