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 in connection with the drugs of a wholly-owned subsidiary passing the Generic Drugs Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 3 December 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

3 December 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.: 2024-65

Shandong Xinhua Pharmaceutical Company Limited

Announcement in connection with the drugs of a wholly-owned subsidiary passing the Generic 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 Zibo Xincat Pharmaceutical Company Limited (hereinafter referred to as "**Xincat Pharmaceutical**"), a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as 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 azithromycin for Suspension (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:	Azithromycin for Suspension
Dosage form:	Dry suspension
Specifications:	0.1g (calculated based on $C_{38}H_{72}N_2O_{12}$)
Drug category:	Prescription drugs
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Case number:	CYHB2450159
Drug approval number:	Guoyao Zhunzi (国药准字) H20094126
Certificate number:	2024B05658
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 February 2024, 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 generic drug, Azithromycin for Suspension, and the application was accepted. In November 2024, Shandong Zibo Xincat Pharmaceutical Company Limited 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.

Azithromycin is a macrolide antibiotic which is suitable for the treatment of mild to moderate infections caused by designated microbial sensitive strains in the following specific conditions: (1) acute episodes of chronic bronchitis bacterial infection caused by Haemophilus influenzae, Moraxella catarrh or Streptococcus pneumoniae; (2) community-acquired pneumonia caused by chlamydia pneumoniae, Haemophilus influenzae, mycoplasma pneumoniae, or Streptococcus pneumoniae; (3) acute otitis media caused by Haemophilus influenzae, Moraxella catarrhal or Streptococcus pneumoniae; (4) acute bacterial sinusitis caused by Haemophilus influenzae, Moraxella catarrhal or Streptococcus pneumoniae; (5) pharyngitis/tonsillitis caused by Streptococcus pyogenes; (6) simple skin and skin structure infections caused by Staphylococcus aureus, Streptococcus pyogenes or Streptococcus agalactis; (7) urethritis and cervicitis caused by Chlamydia trachomatis or Neisseria gonorrhoeae; (8) male genital ulcer disease caused by Haemophilus ducreae (chancroid).

Azithromycin for Suspension belongs to Class B variety of the national medical insurance catalogue. According to relevant data, in 2023 and the first half of 2024, sales of azithromycin preparations in public medical institutions in China amount to approximately RMB 2.15 billion and RMB 1.46 billion respectively.

III. Impact on the Company and risk warning

The passing of consistency evaluation of generic drug quality and efficacy in December 2024 concerning azithromycin dry suspension of Xincat Pharmaceutical, a wholly-owned subsidiary of the Company, is conducive in enriching the Company's anti-infective drugs product line and enhances its core 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
3 December 2024