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**") will publish the "*Announcement on Azithromycin Tablets Having Passed the Generics Consistency Evaluation*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 1 September 2026. 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

31 August 2026 Zibo, the People's Republic of China

As at the date of this announcement, the board of directors of the Company comprises:

Executive Directors:

Mr. He Tongqing *(Chairman)*
Mr. Xu Wenhui
Mr. Hou Ning

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Non-executive Director:

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Azithromycin Tablets Having Passed 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 Xincat Pharmaceutical Company Limited (hereinafter referred to as "**Xincat Pharmaceutical**"), a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited, has recently received the *Notification of Approval of Supplementary Drug Application* (药品补充申请批准通知书) issued under the approval of the National Medical Products Administration in relation to its Azithromycin 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:	Azithromycin Tablets
Dosage form:	Tablets
Specifications:	0.25g (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:	CYHB2550334
Drug approval number:	National Medicine Zhunzi (国药准字) H20083479
Notification number:	2026B05755
Review conclusion:	The Product passed the *Consistency of Quality and Efficacy Evaluation for Generic Drugs*.

II. Other relevant information

In September 2025, Xincat Pharmaceutical submitted application materials to the Center for Drug Evaluation of the National Medical Products Administration (药品审评中心) in connection with the consistency of quality and efficacy evaluation of the generic drug, Azithromycin Tablets, and the application was accepted. In August 2026, the *Notification of Approval of Supplementary Drug Application* was agranted with the conclusion that the Product has passed the *Consistency of Quality and Efficacy Evaluation for Generic Drugs*.

Azithromycin is a macrolide antimicrobial agent used for the treatment of mild to moderate infections caused by sensitive strains of the indicated organisms under the following specific conditions: (1) acute episodes of chronic bronchitis bacterial infection caused by Haemophilus influenzae, Moraxella catarrhalis, 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 catarrhalis or Streptococcus pneumoniae; (4) acute bacterial sinusitis caused by Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae; (5) pharyngitis/tonsillitis caused by Streptococcus pyogenes; (6) simple infections of skin and skin structures caused by Staphylococcus aureus, Streptococcus

pyogenes or Streptococcus agalactiae; (7) urethritis and cervicitis caused by Chlamydia trachomatis or Neisseria gonorrhoeae; and (8) male genital ulcers caused by Haemophilus ducreyi (chancroid).

The Product is listed in the "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)" as a Category A product. According to relevant statistics, the sales of Azithromycin Tablets in China's public medical institutions amounted to approximately RMB670 million in 2025.

III. Impact on the Company and risk warning

The Azithromycin Tablets of Xincat Pharmaceutical having passed the *Consistency of Quality and Efficacy Evaluation for Generic Drugs* in August 2026 is conducive to improving its 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
31August 2026