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 Clarithromycin for Suspension of the Subsidiary Having Obtained Drug Registration Certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 27 August 2025. 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

26 August 2025 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

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Clarithromycin for Suspension of the Subsidiary
Having Obtained Drug Registration Certificate

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 the Company, has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Clarithromycin for Suspension (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:	Clarithromycin for Suspension
Dosage form:	Suspension
Specification:	1.5g
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2303570
Drug approval number:	National Medicine Zhunzi (国药准字) H20255116
Notification number:	2025S02481
Review conclusion:	In accordance with the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and relevant regulation, upon review, the Product conforms with the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labels as well as production process concerning the Product shall be consummated in accordance with relevant documentation. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of drugs.

II. Other relevant information

In December 2023, Xincat Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Clarithromycin for Suspension and the application materials were accepted. In August 2025, Xincat Pharmaceutical obtained the

Drug Registration Certificate, and the review conclusion was that the Product shall be approved for registration.

The Product is indicated for the treatment of infections caused by pathogens that are sensitive to Clarithromycin, including: (i) upper respiratory tract infections: infection of the nasopharynx (tonsillitis, pharyngitis) and paranasal sinuses; caused by Streptococcus pyogenes, Haemophilus influenzae, Moraxella catarrhalis, Streptococcus pneumoniae, Streptococcus aureus, Neisseria gonorrhoeae, Staphylococcus aureus, anaerobic bacteria, etc.; (ii) lower respiratory tract infections: bronchitis, acute lobar pneumonia and pneumonia caused by primary atypical pathogens; caused by Haemophilus influenzae, Haemophilus parainfluenza, Moraxella catarrhalis, Streptococcus pneumoniae, Legionella pneumophila, Bordetella pertussis, Staphylococcus aureus, Mycoplasma pneumoniae or chlamydia pneumoniae, etc. (iii) Skin and soft tissue infections: impetigo, erysipelas, folliculitis, furuncles and infected wounds; caused by Staphylococcus aureus, Streptococcus pyogenes, Propionibacterium acnes, Streptococcus aureus, etc.; and (iv) Acute Otitis Media (AOM): caused by Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae, etc. According to relevant statistics, the sales of Clarithromycin in China's public medical institutions amounted to approximately RMB1.123 billion in 2024.

III. Impact on the Company and risk warning

The obtaining of the *Drug Registration Certificate* in connection with Clarithromycin for Suspension by Xincat Pharmaceutical in August 2025 is conducive to enriching the variety of anti-infective drugs of the Company and enhancing its comprehensive competitiveness.

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
26 August 2025