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 Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution having obtained Drug Registration Certificate*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 12 May 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

11 May 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

Non-executive Directors:

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 Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution 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 Xinhua Pharmaceutical Company Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution (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:	Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution
Dosage form:	Oral solution
Specifications:	100ml: 150mg of ambroxol hydrochloride and 100 μg of clenbuterol hydrochloride
Drug category:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2401549
Drug approval number:	National Medicine Zhunzi (国药准字) H20264248
Certification number:	2026S01462
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 regulations, upon review, the Product conforms with the applicable requirements of drug registration, the drug registration is approved, and the *Drug Registration Certificate* has been issued. The standard of quality, product instructions, labels as well as production processes 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 May 2024, Xinhua 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 Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution and the application materials were accepted. In May 2026, Xinhua Pharmaceutical obtained the *Drug Registration Certificate*, and the review conclusion was that the Product shall

be approved for registration.

The Product is used for the treatment of acute and chronic respiratory diseases (such as acute and chronic bronchitis, emphysema, etc.) caused by cough, viscous sputum, difficult sputum excretion, wheezing, etc.

According to relevant statistics, the sales of Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution in China's public medical institutions amounted to approximately RMB740 million in 2024.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's obtaining of *Drug Registration Certificate* in connection with Ambroxol Hydrochloride and Clenbuterol Hydrochloride Oral Solution in May 2026 will further enrich respiratory system product series for the Company and enhance the Company's comprehensive 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
11 May 2026