

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 Valsartan Capsules having obtained the Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 30 December 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

29 December 2025, Zibo, 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 Directors:

Mr. Xu Lie

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Valsartan Capsules having obtained the 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 (“**Xinhua Pharmaceutical**”, or the “**Company**”) has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Valsartan Capsules (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:	Valsartan Capsules
Dosage form:	Capsules
Specifications:	80mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2402871
Drug approval number:	National Medicine Zhunzi (国药准字)H20256391
Certificate number:	2025S03925
Review conclusion:	In accordance with the <i>Pharmaceutical Administration Law of the People's Republic of China</i> (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, the drug registration is approved and the <i>Drug Registration Certificate</i> 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 September 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 Valsartan Capsules and the application materials were accepted. In December 2025, 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 mild to moderate primary hypertension.

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 Valsartan Capsules in China’s public medical institutions amounted to approximately RMB 1.82 billion in 2024.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical’s obtaining of *Drug Registration Certificate* in connection with its Valsartan Capsules in December 2025 will be conducive to enriching the Company’s product series for the treatment of cardiovascular diseases and enhance its 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**
29 December 2025