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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 Dapagliflozin Tablets having obtained Drug Registration Certificate*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 22 August 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

21 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 Dapagliflozin Tablets 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 “**Xinhua Pharmaceutical**” or the “**Company**”) has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Dapagliflozin Tablets (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:	Dapagliflozin Tablets
Dosage form:	Tablets
Specifications:	10mg (calculated based on $C_{21}H_{25}ClO_6$), 5mg (calculated based on $C_{21}H_{25}ClO_6$)
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2500993, CYHS2500994
Drug approval number:	National Medicine Zhunzi (国药准字)H20265648, National Medicine Zhunzi (国药准字)H20265670
Certificate number:	2026S03042, 2026S03066
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 regulations, 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 March 2025, Xinhua Pharmaceutical submitted application materials to the *Center for Drug Evaluation of the National Medical Products Administration* (药品审评中心) (CDE) concerning the marketing of Dapagliflozin Tablets and the application materials were accepted. In August 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 in adult patients with type 2 diabetes mellitus: (i) as monotherapy to improve glycemic control on the basis of diet and exercise; (ii) as combination therapy with metformin hydrochloride to improve glycemic control in addition to diet and exercise when glycemic control is inadequate with metformin hydrochloride alone; and (iii) when glycemic control is inadequate with insulin alone or when insulin is used in combination with oral antidiabetic drugs, as combination therapy with insulin to improve glycemic control in addition to diet and exercise. The Product is also used in adult patients with heart failure to reduce the risk of cardiovascular death, hospitalization for heart failure, or urgent visits for heart failure in adults with symptomatic chronic heart failure.

The Product is listed in the “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)” as a Category B product. According to relevant statistics, the sales of Dapagliflozin Tablets in China’s public medical institutions amounted to approximately RMB 11.4 billion in 2025.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical’s obtaining of *Drug Registration Certificate* in connection with Dapagliflozin Tablets in August 2026 will further enrich the Company’s product line and help enhance 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
21 August 2026