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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 an “*Announcement on Bumetanide Injection Having Obtained Drug Registration Certificate*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 16 April 2026. The English translation of the relevant announcement 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 of directors of the Company
Shandong Xinhua Pharmaceutical Company Limited
He Tongqing
Chairman

15 April 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 Directors:

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Bumetanide Injection 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 statement or material omission.

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 Bumetanide Injection (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:	Bumetanide Injection
Dosage form:	Injection
Specification:	2ml : 0.5mg; 4ml : 1mg
Drug classification:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Reception number:	CYHS2401640、CYHB2501239; CYHS2401641、CYHB2501238
Drug approval number:	National Medicine Zhunzi (国药准字) H20263884、H20263885
Notification number:	2026S01044、2026S01045
Approval 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, 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, Beijing Minkang Baicao Pharmaceutical Technology Company Limited (北京民康百草

医药科技有限公司)(hereinafter referred to as “Minkang Baicao”) 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 Bumetanide Injection and the application materials were accepted.

In May 2024, Xinhua Pharmaceutical and Beijing Minkang Baicao signed a production technology and holder transfer contract. According to the contract, Beijing Minkang Baicao shall make a one-off transfer of all its *Marketing Authorization Holder* (MAH) rights (including, without limitation, formulation production approval and commercialization rights (including, but not limited to, those relating to product manufacturing, sales and marketing) to Xinhua Pharmaceutical. The total technology transfer fee shall be payable by Xinhua Pharmaceutical to Beijing Minkang Baicao in accordance with staged instalments as stipulated under the contract.

Pursuant to the Rules Governing the Listing of Shares on Shenzhen Stock Exchange (深圳证券交易所股票上市规则) and the articles of association of the Company (公司章程), the present transaction is not required to be submitted for the review and approval of the board of directors or shareholders’ meeting of the Company. The present transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the *Measures for Administration of Material Assets Reorganization of Listed Companies* (上市公司重大资产重组管理办法).

In April 2026, Xinhua Pharmaceutical obtained the Drug Registration Certificate of Bumetanide Injection, and the review conclusion was that the Product shall be approved for registration.

The Product is applicable for treatment of (1) edema-related diseases including congestive heart failure, liver cirrhosis, and kidney diseases (nephritis, nephropathy, and various acute and chronic renal failure caused by various reasons); in particular, this drug may still be effective when other diuretics are ineffective. It can also be used in combination with other drugs to treat acute pulmonary edema and acute cerebral edema, etc. (2) hypertension. In the gradient therapy of hypertension, it is not the first choice for treating primary hypertension, but when thiazide drugs are ineffective, especially when accompanied by renal insufficiency or a hypertensive crisis occurs, this type of drug is particularly applicable; (3) prevention of acute renal failure: used for various reasons causing insufficient renal blood perfusion, such as dehydration, shock, poisoning, anesthesia accidents, and circulatory insufficiency, etc. When correcting the insufficient blood volume and applying it in time, the chance of acute tubular necrosis can be reduced; (4) hyperkalemia and hypercalcemia; (5) dilutional hyponatremia, especially when the blood sodium concentration is lower than 120 mmol/L; (6) syndrome of inappropriate antidiuretic hormone secretion (SIADH); (7) treatment of acute drug poisoning, such as barbiturate poisoning, etc.; and (8) in certain cases where furosemide is ineffective.

Bumetanide Injection 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 Bumetanide Injection in China’s public medical institutions amounted to approximately RMB470 million in 2024.

III. Impact on the Company and risk warning

The obtaining of Drug Registration Certificate in connection with Bumetanide Injection by Xinhua Pharmaceutical in April 2026 will enrich the Company’s pharmaceutical formulation product series and enhancing its competitiveness.

The pharmaceutical sales business is susceptible changes in domestic pharmaceutical industry policies, tendering and procurement processes, changes in 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**

15 April 2026