

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 Donepezil Hydrochloride Orally Disintegrating Tablets of subsidiary having obtained Drug Registration Certificate*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 21 September 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

18 September 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 Donepezil Hydrochloride Orally Disintegrating Tablets of 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 Shandong Xinhua Pharmaceutical Company Limited, has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Donepezil Hydrochloride Orally Disintegrating 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:	Donepezil Hydrochloride Orally Disintegrating Tablets
Dosage form:	Tablets
Specifications:	5mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2500658
Drug approval number:	National Medicine Zhunzi (国药准字)H20266009
Certificate number:	2026S03459
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 February 2025, Xincat 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 Donepezil Hydrochloride Orally Disintegrating Tablets and the application materials were accepted. In September 2026,

Xincat 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, moderate or severe symptoms of Alzheimer's disease.

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 Donepezil preparation in China’s public medical institutions amounted to approximately RMB620 million in 2025.

III. Impact on the Company and risk warning

The obtaining of approval by Xincat Pharmaceutical in September 2026 in connection with its application for the Donepezil Hydrochloride Orally Disintegrating Tablets is conducive to enriching the Company’s product series in the central nervous system field and enhancing the 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**

18 September 2026