**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 Prednisolone Acetate having obtained the *Notification of Approval of Marketing Application for Chemical Active Pharmaceutical Ingredients*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 28 November 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*

27 November 2025, 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. Xu Lie
Mr. Zhang Chengyong

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Stock Code: 000756 Stock Short Name: Xinhua Pharmaceutical Announcement No.: 2025-69

**Shandong Xinhua Pharmaceutical Company Limited**

**Announcement on Prednisolone Acetate having obtained the Notification of Approval of Marketing Application for Chemical Active Pharmaceutical Ingredients**

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 *Notification of Approval of Marketing Application for Chemical Active Pharmaceutical Ingredients* (化学原料药上市申请批准通知书) in connection with its Prednisolone Acetate (hereinafter referred to as the "**Product**") which issued under the approval of the National Medical Products Administration. Relevant information is now announced as follows:

**I. Basic information**

| | |
|---|---|
| API name: | Prednisolone Acetate |
| Registration classification: | Chemical drugs |
| Applicant: | Shandong Xinhua Pharmaceutical Company Limited |
| Application natter: | Application for the Marketing of Domestically Produced Active Pharmaceutical Ingredients |
| Reception number: | CYHS2460218 |
| Registration number: | Y20230001352 |
| Notification number: | 2025YS01039 |
| Review conclusion: | According to the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and applicable regulation, upon review, the Product conforms with applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation. |

**II. Other relevant information**

In March 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation (CDE) of the National Medical Products Administration in connection with the registration for the marketing of domestically produced Prednisolone Acetate, and such application was accepted. In November 2025, Xinhua Pharmaceutical obtained the *Notification of Approval of Marketing Application for Chemical* Active Pharmaceutical Ingredients (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

This Product is mainly used for treatment of allergic and autoimmune inflammatory diseases. It is now widely used to treat active rheumatism, rheumatoid arthritis, systemic lupuserythematosus, severe bronchial asthma, nephrotic syndrome, thrombocytopenic purpura, granulocytopenia, variousrenocortical insufficiency, severe dermatitis, acute leukemia, etc. It is also used in comprehensive treatment of some infections.

According to relevant statistics, the sales of Prednisolone Acetate in China's public medical institutions amount to approximately RMB 100 million in 2024.

**III. Impact on the Company and risk warning**

The obtaing of approval of the Product described above will further enrich the Company's hormone product line and enhance its core 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**

27 November 2025