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**") has published the "Announcement regarding Prednisone having obtained the Notification of Approval of Application for Marketing of Active Pharmaceutical Ingredient" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 28 February 2024. 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

28 February 2024, Zibo, PRC

As at the date of this announcement, the Board 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
Mr. Cheung Ching Ching, Daisy

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2024-09

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Prednisone having obtained the Notification of Approval of Application for Marketing of Active Pharmaceutical Ingredient

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 Application for Marketing of Active Pharmaceutical Ingredients* (化学原料药上市申请批准通知书) issued by the National Medical Products Administration in relation to prednisone (hereinafter referred to as the "**Product**"). Relevant information is now announced as follows:

1. Basic information

Drug name:	Prednisone
Dosage form:	Active Pharmaceutical Ingredients
Registration category:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for marketing of domestic produced chemical Active Pharmaceutical Ingredients
Case number:	CYHS2260214
Registration number:	Y20220000275
Notification number:	2024YS00145
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 applicable regulation, upon review, the Product conforms with relevant drug registration requirements and its production is approved. Quality standards, labelling as well as production techiques shall be implemented as enclosed therein.

2. Other relevant information

In April 2022, Xinhua Pharmaceutical submitted the registration application materials to the National Medical Products Administration (国家药品监督管理局) concerning the application for registration for marketing of domestically produced chemical Active Pharmaceutical Ingredigents in connection with its prednisone, and the application materials were accepted. In February 2024, Xinhua Pharmaceutical received the *Notification of Approval for Application for Marketing of Active Pharmaceutical Ingredients* with the review conclusion that the production of the Product has been approved.

This product has been already been marketed both domestically and internationally. The prednisone tablet of West-Ward Pharmaceuticals International Ltd is a similar drug type which is recognised internationally and has been published in the *Orange Book* of the United States of America, being referenced preparations as

published by the National Medical Products Administration. The prednisone tablets of that company has subsequently been transferred to Hikma Pharmaceuticals USA Inc..

The Product has anti-inflammatory and anti-allergic effects, can inhibit the proliferation of connective tissue, reduce the permeability of capillary walls and cell membranes, reduce inflammatory exudation, and inhibit the formation and release of histamine and other toxic substances.When used in combination with a large amount of antibiotics in severe toxic infections, it can have sound cooling, detoxification, anti-inflammatory or anti-shock effects, and can promote symptom relief.

This product is an adrenocortical hormone drug, and its tablets have been included in the National Essential Medicines Catalogue (2018 edition), and belongs to the category A variety in the "*National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)*".According to relevant statistical data, global sales of prednisone preparations amounted to approximately US$408 million in 2023, with consumption of approximately 43.2 tons in Active Pharmaceutical Ingredients.

3. Impact on the Company and risk warning

The approval of the Product will further enrich the Company's hormone product series and further enhance the Company's competitiveness.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, 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

28 February 2024