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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 Co., Ltd. (the "**Company**") has published the "Announcement on Meloxicam Capsules passing the generics consistency evaluation" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 27 March 2023, the English version 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 March 2023, 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. Cong Kechun

Mr. Xu Lie

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Lo Wah Wai

Mr. Ling Peixue

Shandong Xinhua Pharmaceutical Company Limited**Announcement on Meloxicam Capsules passing the generics consistency evaluation**

The Company and the 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 Notice of Approval of Supplementary Drug Application (《药品补充申请批准通知书》) from the National Medical Products Administration in relation to the approval of Meloxicam Capsules (美洛昔康胶囊) (hereinafter referred to as the “**Product**”), which has passed the “Consistency of Quality and Efficacy Evaluation for Generic Drugs” (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug Name: Meloxicam Capsules

Dosage form: Capsules

Specifications: 7.5mg

Drug Category: Prescription Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Consistency of Quality and Efficacy Evaluation for Generic Drugs

Reception Number: CYHB2151097

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20010002

Notification number: 2023B01462

Approval Conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In December 2021, Xinhua Pharmaceutical submitted registration materials for the consistency of quality and efficacy evaluation for generic drugs of Meloxicam Capsules to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) and was accepted. In March 2023, the Company was granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that the Company has passed the consistency of quality and efficacy evaluation for generic drugs.

Meloxicam was developed by the Boehringer Ingelheim (German). It has successively developed tablet, capsule, and other dosage forms, and has been marketed in France, the United Kingdom, Switzerland, Sweden, and other countries. The capsule product name is Mobic.

Meloxicam is an enolic acid nonsteroidal anti-inflammatory drug that is suitable for the treatment of rheumatoid arthritis and painful osteoarthritis (arthropathy, degenerative osteoarthritis). Meloxicam Capsules belongs to the category B variety of the “National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2020 Edition)”(《国家基本医疗保险、工伤保险和生育保险药品目录(2020年)》).

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's Meloxicam Capsules has passed the consistency of quality and efficacy evaluation for generic drugs in March 2023, which will help further enhance the Product's market competitiveness.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest rationally and pay attention to investment risks.

By Order of the Board

Shandong Xinhua Pharmaceutical Company Limited

27 March 2023