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# FOSUN PHARMA

## 复星医药

上海復星醫藥（集團）股份有限公司

**Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\***

*(a joint stock limited company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 02196)**

### CLARIFICATION ANNOUNCEMENT ON MEDIA REPORTS

This announcement is made by Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* (the “**Company**”, together with its subsidiaries, the “**Group**”) to clarify the recent media reports.

Recently, Chongqing Food and Drug Administration (“**Chongqing FDA**”) received a letter regarding the “Material Breach of the Drug Administration Law by the Pharmaceutical Company of Chongqing Pharmaceutical Research Institute” (the “**Letter**”) in its public mailbox. In response to the Letter, the Company, after an internal investigation, would like to make the following clarifications:

- (1) In May 2016, U.S. Food & Drug Administration (“**FDA**”) conducted an inspection at the factory of Chongqing Pharmaceutical Research Institute Co., Ltd.\* (重慶醫藥工業研究院有限責任公司) (“**Chongqing Research Institute**”), a subsidiary of the Company, located in Tushan Road, Nan’an District, and issued a warning letter requesting to rectify the insufficient standardisation of lab information identified during the course of an inspection in relation to active pharmaceutical ingredients (APIs) at its QC lab. Addressing the rectification request, Chongqing Research Institute has dealt with and restructured the key leaders and the relevant responsible personnel at that time in a serious manner, and is active in the progress of the relevant rectification works in order to pass the on-site inspection by FDA.

In November 2017, FDA conducted a pre-approval examination on the quality control system of Chongqing Research Institute Pharmaceutical Co., Ltd.\* (重慶醫工院製藥有限責任公司) (“**Research Institute Pharmaceutical**”), the subsidiary of Chongqing Research Institute, at a new site located in Changshou District. After examination, FDA issued a Form 483 in respect of API aripiprazole, for its deficiency of invalidated OOS result in the testing (deviation investigation). Research Institute Pharmaceutical has already been in the process of rectification under the standardisation guidance of FDA.

- (2) In addition, according to the results of an internal investigation conducted by Research Institute Pharmaceutical, all existing products are manufactured in accordance with approved production process. At production stage, adjustments to the production process have been approved by or filed with the relevant drug regulatory authorities.
- (3) To accommodate the operating requirements, Chongqing Research Institute has transferred to Research Institute Pharmaceutical the approvals of APIs aripiprazole and pemetrexed disodium products in 2016, and the approval of API iron sucrose products in 2018. On-site inspections have been conducted and these transfers have been approved by the drug regulatory authorities.
- (4) Research Institute Pharmaceutical has submitted the application for a change of production process of its API aripiprazole and products supplied to Shanghai Zhongxi Sunve Pharmaceutical Co., Ltd.\* (上海中西三維藥業有限公司) in 2018 are for solely its research of preparations.
- (5) Chongqing FDA has commenced an investigation on the matters reflected in the Letter. On 23 August 2018, Chongqing FDA made an unannounced inspection at Chongqing Research Institute, the conclusive opinion of which is yet to be finalised.

The Group places great emphasis on the quality and risk management throughout the life cycle of its products. Therefore, the Group has adopted and implemented quality and safety control mechanisms and adverse drug reaction monitoring mechanisms at each stage of the production chain from R&D to sales of products, so as to ensure the R&D, production, sales, pulling off shelf and recall of products are conducted safely and properly. The Company will closely monitor the developments of the event as mentioned in the Letter, and will comply with its disclosure obligation.

The Company wishes to remind the shareholders and potential investors of the Company to refer to announcements posted on the websites of The Stock Exchange of Hong Kong Limited (<http://www.hkexnews.hk>) and the Company for information on the Group. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By order of the Board  
**Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\***  
**Chen Qiyu**  
*Chairman*

Shanghai, The People's Republic of China  
31 August 2018

*As at the date of this announcement, the executive directors of the Company are Mr. Chen Qiyu, Mr. Yao Fang and Mr. Wu Yifang; the non-executive directors of the Company are Mr. Wang Qunbin, Mr. Wang Can, Ms. Mu Haining and Mr. Zhang Xueqing ; and the independent non-executive directors of the Company are Mr. Cao Huimin, Mr. Jiang Xian, Dr. Wong Tin Yau Kelvin and Mr. Wai Shiu Kwan Danny.*

\* *for identification purposes only*