# TIANJIN ZHONG XIN PHARMACEUTICAL GROUP CORPORATION LIMITED

(Company Registration No. 120000000004711) (Incorporated in the People's Republic of China)

#### UPDATE ON RECALL OF A PRODUCT FROM HONG KONG

The board of directors (the "Board") and every individual directors of Tianjin Zhong Xin Pharmaceutical Group Corporation Limited (the "Company") hereby confirm that they will individually and collectively accept full responsibility for the accuracy of the information given in this announcement, and confirm, having made all reasonable enquiries, that to the best of their knowledge and belief, the facts stated in this announcement are fair and accurate in all material respects as at the date of this announcement, and that there are no material facts the omission of which would make any statement in this announcement misleading.

# 1. INTRODUCTION

The Board refers to the previous announcements by the Company on 20 April 2016 and 22 April 2016 in relation to the recall of a product from Hong Kong (the "**Prior Announcements**").

Capitalised terms not defined herein shall bear the same meaning as terms defined in the Prior Announcements.

On 19 April 2016, the Company became aware of an announcement released by the Hong Kong Department of Health, mentioning that the Product (batch number:MH-151) contains small amounts of paracetamol. The China Food and Drug Administration also released an announcement on 21 April 2016 stating that it will begin investigations on the Product (the "CFD Announcement"). In the mean time, the Tianjin Market Supervision Committee has inspected the Long Shun Rong Pharmaceutical Factory where the Product is manufactured (the "LSR Factory"), tested the samples, and requested that the LSR Factory cease production until any problems are rectified. The Company launched internal investigations on 19 April 2016, and wishes to update on the following.

### 2. COURSE OF EVENTS

The registration of the Product sold in Hong Kong (registration number: HKP-00056) was completed by Ming Hua Company (an overseas agent of the Group) and the certification of registration is held by Ming Hua Company. The Product is sold only in Hong Kong and not in the mainland of the People's Republic of China. A total of approximately 4600 boxes of the Product were involved in the investigations, which were produced on 17 June 2014, of which approximately 3100 boxes were delivered to Ming Hua Company.

Previously, in December 2014, the LSR Factory had discovered that 2 different products, namely the Product and *Jingzhi Yinqiao Jiedu Pian* (a product with a different prescription and different certificate number), were produced in the same production line. This resulted in the Product being contaminated by *Jingzhi Yinqiao Jiedu Pian*, which is an exported product, and contains paracetamol as one of its legally approved ingredients. Pursuant to the above, on 11 December 2014, the Company had destroyed all the Product in its inventory, and requested for the destruction of the Product which had already been delivered to Ming Hua Company. However, pursuant to the recent internal investigations, it was revealed that Ming Hua

Company had sent samples of the Product (which should have been destroyed) to the Hong Kong Standards and Testing Center Co., Ltd. for inspection on 21 January 2015 and 23 April 2015. The inspection results had showed that no paracetamol was detected. Therefore, Ming Hua Company continued selling the remaining Product which should have been destroyed. Ming Hua Company has strictly complied with the recall requirements of the Hong Kong Department of Health, pursuant to which 314 boxes have been recalled as at 24 April 2016. As of the date of this announcement, there have been no reports of any adverse reactions to the Product. The recall of the Product by Ming Hua Company is in accordance with the requirements of the Hong Kong Department of Health. Pending the final destruction of the Product, Ming Hua Company has sealed up the Product, filled in the form requested by the Hong Kong Department of Health and reported the status of the recall of the Product to the Chinese Medicine Group of Hong Kong Chinese Medicine Council.

# 3. CFD ANNOUNCEMENT

The China Food and Drug Administration released the CFD Announcement on 21 April 2016, stating that any contamination of the Product with paracetamol due to incomplete clearance of the production line shared with *Jingzhi Yinqiao Jiedu Pian* is a violation of pharmaceutical good manufacturing practices. This reflects a serious lapse in the quality management of the products manufactured by the LSR Factory. Therefore, the China Food and Drug Administration has instructed the Tianjin Market and Quality Supervision Committee to order the LSR Factory to cease its production for review and to recall the Product. In addition, the China Food and Drug Administration and Tianjin Market and Quality Supervision Committee will initiate investigations on the non-compliances of the LSR Factory, expand the scope of the samples testing of the relevant products of the LSR Factory, and will keep the public updated on the above.

Pursuant to the CFD Announcement, the Company has procured the LSR Factory to cease its production, recall the Product from Hong Kong, as well as actively cooperate with any investigations. The Tianjin Market and Quality Supervision and Management Committee and the Tianjin Binhai New Area Market and Quality Supervision Administration will be reviewing the situation before making a decision on whether investigations on the LSR Factory will be initiated. As at the date of this announcement, the Company has not received any notice about the commencement of investigations on the LSR Factory.

# 4. MEASURES TO BE TAKEN BY THE COMPANY

This incident reflects an issue in the management of the Company's operations. To avoid the similar incidents from occurring in the future and to ensure the safety of consumers, the Company will take the following measures:

- (i) The Company will strictly comply with any request from the China Food and Drug Administration, Tianjin Market and Quality Supervision Committee and Tianjin Binhai New Area Market and Quality Supervision Administration, including procuring the LSR Factory to cease its production, recall the Product from Hong Kong, as well as actively cooperate with any investigations.
- (ii) The Company will conduct a comprehensive self-inspection.
- (iii) The Company will be sending its staff to Hong Kong to supervise Ming Hua Company in the recall and destruction of the Product.

- (iv) The Company has suspended the exports of all the Chinese medicine produced in the LSR Factory to Hong Kong and continued comprehensive investigations to determine if there are any remaining incidents of contamination of Chinese medicine with paracetamol. As at the date of this announcement, the inspections by the relevant authorities and the Company's self-inspection have not resulted in paracetamol being detected in any other Chinese medicine exported by the Company to Hong Kong.
- (v) The Company will assume all the responsibilities and obligations as a result of the investigations.

# 5. IMPACT ON THE COMPANY

The sales revenue of the Product in Hong Kong was RMB100,000 in the financial year ended 31 December 2015 ("**FY2015**"), accounting for a small part of the total sales revenue of the Company, so the recall of the Product will have no direct impact on the overall businesses of the Company. As of now, there have been no reports of any adverse reactions to the Product.

The sales revenue arising from the exports of the Chinese medicine produced in the LSR Factory to Hong Kong was RMB2,200,000, accounting for 0.3% of the audited sales revenue of the Company in FY2015. Therefore, the suspension of the exports of all the Chinese medicine produced in the LSR Factory to Hong Kong will not have a large impact on the Company's business as a whole.

The total sales revenue of the LSR Factory was RMB 242,490,000, accounting for 3.42% of the audited sales revenue of the Company in FY2015. The total net profit of the LSR Factory was RMB4,810,000, accounting for 1.07% of the audited net profit of the Company in FY2015. The main products of the LSR Factory are *Zi Long Jin Pian* and *Long Qing Pian*. Due to the recall of the Product, the LSR Factory will cease its production for review, which will affect the production and sales of the LSR Factory. However the Company is of the view that the cessation of the LSR Factory's production is necessary to address the quality risks and will be beneficial to the Company's reputation and its long-term development. The Company will guide the LSR Factory to adjust its production schedule so as to still achieve the annual production target in order to minimize the overall adverse impact.

The Company is aware that the safety of the Company's products shall always be paramount, and the Company will treat the recall of the Product and the improvement of its management as the top priority to rectify the issues arsing from this recall of the Product. Therefore, the Company has procured the LSR Factory to actively cooperate with the relevant authorities for inspections and complete the review as soon as possible.

In order to protect the interests of the shareholders of the Company and to avoid unusual fluctuations in the Company's share price, the Company has applied for a trading halt since 22 April 2016. The Company will be requesting for resumption of trading on 27 April 2016.

The Company will make further announcements in due course as and when there are material developments on the above.

By order of the Board 26 April 2016