

裕利股份有限公司 函

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受文者：天主教中華聖母修女會醫療財團法人\*

發文日期：中華民國111年09月07日

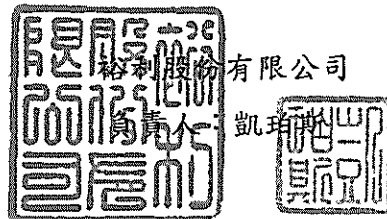
發文字號：111 裕字-第001403號

主旨：本公司銷售之產品「FUNGIZONE INTRAVENOUS INJECTION(防治黴靜脈凍晶注射劑)」，衛署藥輸字第012258號」到貨延遲事宜，如說明段。

說明：

- 一、本公司銷售之產品「FUNGIZONE INTRAVENOUS INJECTION(防治黴靜脈凍晶注射劑)」，衛署藥輸字第012258號」，承蒙 貴院採用特此致謝。
- 二、接獲原製造廠通知，上述產品因國外製造廠通知交付出貨可能延遲至10月中。依照原製造廠通知到貨預估可出貨日期，再加上航空物流安排，貨物預計10月底至11月初可到台灣。冀恢復供貨後能盡快補足庫存，以利病人治療使用。
- 三、依據原製造廠正式告知公文，延遲原因：因原料製程調整，雖未影響相關品質，但在未及時與成品製造端充分告知下，品管控制端需重新檢視相關品質查驗結果，進而導致製造時程延宕。目前成品完成目標時間預定在9月16日，預計10月10日能發貨出廠。
- 四、特此通知，造成不便之處，懇請見諒，並請繼續支持本公司為禱。

附件：原製造廠公文。



CHEPLAPHARM Arzneimittel GmbH \_ Ziegelhof 24 \_ 17489 Greifswald \_ Germany

Greifswald, September 1st, 2022

### Current out of stock situation of Fungizone 50MG In Taiwan

To whom it may concern,

This is to inform you that we are currently not able to perform any deliveries of FUNGIZONE 50MG to Taiwan. While we originally prepared for a delivery of the product to Taiwan in July, at the time of release major deviations were detected, that require further investigation:

Due to miscommunication, changes in the manufacturing process of the API Amphotericin B were not communicated to the finished product manufacturer in time. The changes were assessed as of no regulatory concern and there was no impact on API quality parameters. Nevertheless, a formal evaluation of the impact of these changes on the finished product and its manufacturing process needs to be performed. Release of finished product batches has accordingly been suspended until this evaluation is completed. There is no expected impact on the quality, safety and efficacy of the drug product. The held-up batches are the first to use API produced with the updated process.

As of today, the finished product manufacturer target to release the product by Sep. 16th, we estimate kick of the delivery by October 10th, 2022. As we are fully aware of the urgency of this shipment and want to make sure it reaches the Taiwanese patients as soon as possible we will arrange for a direct delivery.

Kind regards

Cheplapharm

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BANK DETAILS  
ING Bank \_ IBAN: DE73 5002 1000 0018 0077 0001 \_ SWIFT Code: INGBDE33  
UniCredit Bank - Hypovereinsbank \_ IBAN: DE44 2003 0000 0000 0000 0000 31 \_ SWIFT Code: HYVEDE33

REGISTERING COURT  
Stralsund \_ HRB 5896

