M111546-10/13

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10月07日

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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延遲至11月初。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12月中可發貨至 貴院。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，延遲原因不變但因品管部門對於新原料製造的品質查驗所需時間比預期較長。故再次通知需延至11月初始能完成成品檢驗所需作業，並預計在11月10號核准發貨予台灣。估算年底的航班安排情況，預計需至12月初到貨台灣並在當月中出貨至 貴院。

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。

裕利股份有限公司
負責人：凱瑞斯

CHEPLAPHARM

CHEPLAPHARM Arzneimittel GmbH _ Ziegelhof 24 _ 17489 Greifswald _ Germany

Greifswald, October 5th 2022

Update on current out of stock situation of Fungizone 50MG In Taiwan

To whom it may concern,

This Is to Inform you that we, the CHEPLAPHARM Arzneimittel GmbH located in Ziegelhof 24, 17489 Greifswald, 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. While the corresponding data has been thoroughly surveyed and no impact on quality, safety and efficacy of the finished product could be detected, a final risk assessment is currently being prepared to finalize the batch release.

As this final assessment is still ongoing, we regret to inform you that our Initial timeline of a release of goods by September 16th and a kick-off of the delivery to Taiwan by October 10th Is delayed. As of today, we estimate that the release of products by the CMO will take until the end of October, which would result in a kick-off of the delivery to Taiwan until November 10th. We thank you in advance for your understanding and will inform you on any new developments immediately.

Kind regards

Cheplapharm

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REGISTERING COURT
Stralsund _ HRB 5898