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受文者：天主教中華聖母修女會醫療財團法人\*

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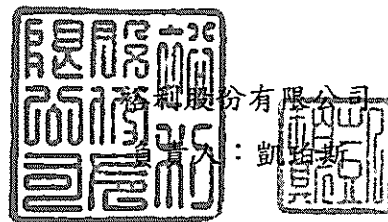
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主旨：本公司銷售之產品「FUNGIZONE INTRAVENOUS INJECTION(防治黴靜脈凍晶注射劑)」，衛署藥輸字第012258號」到貨延遲事宜，如說明段。

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，上述產品因原料變更致成品化驗相關作業須相對應變更而延遲到貨至12月中乙事，國外製造廠來信通知相關檢驗時間比預期長，但有信心在11月底完成所有檢驗項目，並於12月上旬回復供貨台灣市場。
- 三、依據原製造廠通知預估12月上旬的發貨時程，考量年底國際航班運載情況，預計12月底到貨台灣、明年1月10號前完成出貨準備。
- 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, November 1st 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 undergoing, we regret to inform you that our updated timeline that the release of goods by the CMO will end of October and a kick-off of the delivery to Taiwan until November 10th cannot be upheld. As of today, we are assuming the topic could be fully solved by end of November, with a kick-off of delivery in early December this year, but we will update you again once a full delivery plan has been settled. We thank you in advance for your understanding and will inform you on any new developments immediately.

Kind regards

Cheplapharm

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BANK DETAILS  
ING Bank \_ IBAN: DE73 5002 1000 0018 1107 06 \_ SWIFT Code: INGBDE33XXX  
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