澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

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由
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致: 醫生、藥劑師及其他衛生專業人士
Para/To: Physicians, pharmacists and other healthcare professionals
主題: 關於lenalidomide(Revlimid®)安全性的最新資訊
Ass./Subject: Latest safety update on lenalidomide(Revlimid®)
頁數: 1/2
Nº folhas/N.pages:

隨件附上一則關於lenalidomide(Revlimid®)安全性的最新資訊, 請醫生、藥劑師及其他衛生專業人士參閱, 如台端懷疑由上述或其他藥物引致的任何不良反應, 請以下列任一方式向本廳通報：

- 網上通報 - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- 郵寄 - 澳門士多鳥拜斯大馬路 51號 華仁中心二樓
- 傳真 – 28524016

通報人士可親臨藥物事務廳索取或在http://www.ssm.gov.mo/design/services/serpt_chn.pdf網址上下載通報表格。如有任何疑問, 請於辦公時間致電85983517或85983439與藥物監測暨管理處楊燕雯藥劑師或林俊耀藥劑師聯絡, 倘遇緊急的情況, 亦可於非辦公時間傳呼85008068。

謹祝 台安!

Attached herewith is the latest safety update about lenalidomide(Revlimid®). If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of the above or any other medication, please report through any of the following methods：

- Online - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2nd Floor, Macao S.A.R., China
- Fax to - 853-28524016

The report form can be collected in person at Department of Pharmaceutical Affairs or downloaded from the website designated as http://www.ssm.gov.mo/design/services/serpt_chn.pdf. Should you have any query, please contact Ms. Beatrice Young or Mr. Jeffrey Lam at 8598-3517 or 8598-3439 respectively from the Division of Pharmacovigilance and Pharmacoeconomics during office hours. In case of urgent situations during off hours, please page 85008068.

Thanking you in advance for your attention!

藥物事務廳代廳長
Acting Chief of Department of Pharmaceutical Affairs

吳國良
Ng Kuok Leong

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主題： 關於lenalidomide(Revlimid®)安全性的最新資訊
Subject： Latest safety update on lenalidomide(Revlimid®)

Lenalidomide(Revlimid®)爲一種能抑制血管增生和抗紅細胞生成並具有免疫調節作用的抗腫瘤藥物, 與地塞米松(dexamethasone)併用治療罹患多發性骨髓瘤(multiple myeloma)的病人, 英國藥物管理局(MHRA)通知衛生專業人士關於該藥安全性的最新資訊。上市後數據的結果顯示該藥可能進一步增加多發性骨髓瘤病人出現靜脈和動脈血栓栓塞的風險, 包括心肌梗死、腦血管事件(如中風和腦缺血性病發)、深部靜脈栓塞和肺動脈栓塞等。根據上述結果, 使用Revlimid®時部份的血栓栓塞性疾病和死亡個案應當是可以避免的, 因此, 建議醫生、藥劑師及其他衛生專業人士：

- 密切監測正使用Revlimid®的多發性骨髓瘤病人, 有否出現動脈和靜脈血栓栓塞的症狀；
- 控制病人其他引起血栓栓塞的危險因子, 包括建議病人戒煙、控制高血壓和高血脂；
- 對服用Revlimid®的病人作仔細的風險效益評估後, 可考慮處方預防血栓的藥物, 特別對具有多種血栓危險因子的病人；
- 對正在使用Revlimid®治療的病人須謹慎處方可引起血栓栓塞的藥物, 如雌激素和紅細胞生成素；
- 如病人開始出現血栓栓塞的症狀, 應停止使用Revlimid®, 並使用抗凝血劑處理病人的血栓栓塞使病人的病情穩定, 在評估風險和效益後, 可由最初的劑量重新使用Revlimid®, 此後需於整個治療期間併用抗凝血劑。

藥物監測暨管理處

The British Medicines and Healthcare-products Regulating Agency(MHRA) informed healthcare professionals about the latest update on lenalidomide(Revlimid®), an immunomodulating antineoplastic with antiangiogenic and antierythropoietic properties, is indicated in combination with dexamethasone for multiple myeloma patients. Results from postmarketng data suggests the drug may further elevate the increased risk of both venous and arterial thromboembolic events namely myocardial infarction and cerebrovascular accident(e.g. stroke and transient ischemic attack), deep venous thrombolis and pulmonary embolism in patients with multiple myeloma. In light of this observation and as some of the morbidity and mortality cases attributable to thromboembolism upon lenalidomide administrastion may be preventable, the following recommendation are advised for the physicians, pharmacists and other healthcare professionals：

- monitor closely patients who are receiving Revlimid® for multiple myeloma for signs of arterial and venous thromboembolic events;
- manage patients' modifiable risk factors for thromboembolic events e.g. smoking cessation; control of hypertension and hyperlipidemia wherever possible;
- consider prescribing thromboprophylactic medication particularly in patients with multiple thrombotic risk factors while they are being treated with Revlimid® upon careful assessment of the balance of risks and benefits for individual patients;
- caution use of thromboembolic drugs e.g. estrogens and erythropoietic agents while patients are on Revlimid®treatment;
- discontinue Revlimid® when patients started to experience thromboembolic events. Once the patient has been stabilized on the anticoagulants and when his/her complications of the thromboembolic event have been managed, restart Revlimid® at the original dose after a reassessment of treatment risks and benefits. Anticoagulation should then be continued throughout the course of Revlimid® treatment.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website：
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON108684