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
De/From:
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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tamoxifen和Spiriva® Respimat(tiotropium)安全性的最新資訊
Ass./Subject: Latest safety updates on tamoxifen and Spiriva® Respimat(tiotropium)
頁數: 1/2
N° folhas/N.pages:

隨件附上兩則分別關於tamoxifen及Spiriva® Respimat(tiotropium)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 are the latest safety updates on tamoxifen and Spiriva® Respimat(tiotropium) for your reference. 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, Department of Pharmaceutical Affairs

吳國良
Ng Kuok Leong

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- **併用CYP2D6抑製劑對服用tamoxifen病人的影響**

Tamoxifen是一選擇性雌激素受體調節劑(SERM), 用作緩解或輔助治療雌激素受體陽性的停經前或停經後的乳癌婦女。該藥爲一前藥, 需要經由CYP2D6轉化爲活性代謝物。近期一項在併用SSRI類抗抑鬱藥和tamoxifen的婦女中進行的大範圍群組研究(cohort study)指出, 乳癌的死亡率隨著併用paroxetine(一強效CYP2D6抑制劑)的時間增長而增加, 但並沒有在其他SSRIs中發現相同情況。基於上述相互作用機制及現有的證據, 建議醫生及其他衛生專業人士, 對於服用tamoxifen的乳癌病人, 應儘可能避免併用抑制CYP2D6的藥物。

- **Spiriva® Respimat的最新安全性資訊**

近期一項安全性研究結果指出, 相對於服用安慰劑的病人, 服用Spiriva® Respimat(tiotropium)的慢性阻塞性肺疾病(COPD)病人, 其肺功能、疾病進程以及生活質量都有所改善, 然而, 所有原因的死亡率(all-cause mortality)卻增加了, 其中患有心律疾病的病人, 死亡數字顯著增加, 然而, 在整體分析後並不具有統計學上的顯著性。上述結果的原因目前還不清楚, 可能是由隨機因素造成。目前, 建議對已知患有心律疾病的病人, 應謹慎使用Spiriva® Respimat, 並且不要超出說明書所指示的每日劑量。

藥物監測暨管理處

- **Effect of tamoxifen in patients treated with potent CYP2D6 inhibitors**

Tamoxifen is a selective estrogen-receptor modulator(SERM) indicated for palliative and adjuvant treatment of estrogen-receptor-positive breast cancer in premenopausal and postmenopausal women. Tamoxifen is a prodrug, and the formation of the active metabolite is mediated by the CYP2D6 enzyme. A population-based cohort study on SSRI antidepressants and breast-cancer mortality in women receiving tamoxifen found that the risk of death from breast cancer increased with the length of concomitant treatment with paroxetine—a potent inhibitor of CYP2D6, but not with other SSRIs. Given the strong mechanistic model and overall weight of evidence it is recommended that concomitant use of drugs that inhibit the CYP2D6 enzyme should be avoided whenever possible in patients treated with tamoxifen for breast cancer.

- **Latest safety update on Spiriva® Respimat**

A recently completed safety study that compared Spiriva® Respimat(tiotropium) with placebo in patients with COPD found that lung function, COPD exacerbations, and quality of life were improved by Respimat, but a numerical increase was seen in all-cause mortality compared with placebo, a significant excess in mortality was observed in patients with known cardiac rhythm disorders. However, pooled analyses found that the result is not statistically significant. The underlying reason is unclear, and may be a chance finding. Presently, it is recommended that Spiriva® Respimat should be used with caution in patients with known cardiac rhythm disorders, and the recommended once-daily dose on the package insert should not be exceeded.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website：
http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con099854.pdf