



**PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局**

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貴處檔號

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圖文傳真

**C/O Drug Office
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Landmark East 友邦九龍大樓
20樓2002-05室**

1st March 2022

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

**New Warnings for Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin-
Norepinephrine Reuptake Inhibitors (SNRIs) and Vortioxetine**

On 21st February 2022, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings for pharmaceutical products containing SSRIs, SNRIs (examples are provided in Annex) or vortioxetine by the drug regulatory authorities of Australia, Canada, the European Union, Singapore and the United Kingdom, and decided that the sales pack labels and / or package inserts of relevant registered products should include the following new safety information (or equivalent) as appropriate:

(I) For SSRIs and SNRIs

(A) Risk of long-lasting sexual dysfunction

“Warnings and Precautions

Sexual Dysfunction

Selective serotonin reuptake inhibitors (SSRIs)/ Serotonin-norepinephrine reuptake inhibitors (SNRIs) may cause symptoms of sexual dysfunction. There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs/SNRIs.”

(B) Risk of postpartum haemorrhage

“Special warnings and precautions for use

Abnormal bleeding/haemorrhage

SSRIs/SNRIs may increase the risk of postpartum haemorrhage.

Fertility, pregnancy and lactation

Pregnancy

Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRIs/SNRIs exposure within the month prior to birth.

Undesirable effects

Postpartum haemorrhage is listed as an adverse reaction under reproductive system and breast disorders with frequency “not known”.*

**This event has been reported for the therapeutic class of SSRIs/SNRIs.”*

(II) For sertraline¹

Risk of microscopic colitis

“Adverse effects

Post-marketing experience

Microscopic colitis is listed as an adverse effect under gastrointestinal disorders with frequency “unknown”.”

(III) For vortioxetine

¹ Pharmaceutical products containing sertraline, which is an SSRI, should also include new safety information (or equivalent) (A) Risk of long-lasting sexual dysfunction and (B) Risk of postpartum haemorrhage as stated above.

Risk of postpartum haemorrhage

“Special warnings and precautions for use

Haemorrhage

Selective serotonin reuptake inhibitors (SSRIs)/ Serotonin-norepinephrine reuptake inhibitors (SNRIs) may increase the risk of postpartum haemorrhage, and this risk could potentially apply also to vortioxetine.

Fertility, pregnancy and lactation

Pregnancy

Observational data have provided evidence of an increased risk (less than 2-fold) of postpartum haemorrhage following exposure to an SSRI or SNRI within the month prior to birth. Although no studies have investigated an association between vortioxetine treatment and postpartum haemorrhage, there is a potential risk, taking into account the related mechanism of action.”

You are therefore required to review and revise, if necessary, the sales pack labels and / or package inserts of the concerned products registered by your company to ensure that the products comply with the above new requirements. The revised sales pack labels and / or package inserts should be submitted to the Committee for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not renewed by the Committee.

If you have any enquiries on the above issue, please contact Ms. Queenie CHAN at 3974 4147.

Yours faithfully,



(T.K. YIM)
Secretary,

Pharmacy and Poisons (Registration of
Pharmaceutical Products and Substances:
Certification of Clinical Trial/Medicinal Test)
Committee

c.c. 7-15/3, Product Files

TK/QC

Annex

Examples of SSRIs include citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline, etc.

Examples of SNRIs include desvenlafaxine, duloxetine, milnacipran and venlafaxine, etc.