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

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

Tel. No. : 3974 4133
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圖文傳真

C/O Drug Office
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24th December 2021

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Tramadol

On 13th December 2021, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings about the risk of hallucinations for pharmaceutical products containing tramadol by Health Canada, as well as related safety labelling information as approved by the drug regulatory authorities of Australia, the European Union, Singapore, the United Kingdom and the United States, and decided that the sales pack labels and / or package inserts of such registered products should include the following new safety information (or equivalent) as appropriate:

> *"**Adverse Reactions***
>
> *Hallucinations are listed as adverse reactions under central nervous system with incidence less than 1%, possibly causally related in clinical trials and/or reported in post-marketing experience.*
>
> ***Other Adverse Experiences Previously Reported in Clinical Trials or Post-Marketing Reports***

Adverse events which have been reported with the use of tramadol products include: hallucinations (auditory and visual)

Hallucinations: Visual and auditory hallucinations have been reported at therapeutic doses of tramadol, during post-marketing experience, in a higher rate in elderly patients compared to younger patients. This is consistent with potential risk factors of polypharmacy, hepatic and renal impairment, and comorbid conditions being more common among elderly patients."

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