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

Your Ref. :
貴處檔號

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23rd June 2020

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Domperidone Products

On 16th June 2020, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest recommendation for dosage and treatment duration as well as warnings for domperidone-containing products by the drug regulatory authorities of the United Kingdom, European Union, Canada, Australia and Singapore, and decided that such products should no longer be indicated for use in children and adolescents younger than 12 years of age or those weighing less than 35kg. Therefore, the labels and package inserts of such products should be updated to restrict the use in adults and adolescents 12 years of age and older and weighing 35kg or more.

Domperidone should also be used at the lowest effective dose for the shortest possible duration. Accordingly, the sales pack labels and / or package inserts of registered pharmaceutical products containing domperidone should be updated to include the treatment duration as well as the safety information related to cardiovascular risks and other contraindications as follows (or equivalent):

(i) *Domperidone should be used at the lowest effective dose for the shortest duration and should not normally be used for longer than one week.*

(ii) *Under "Dosage and Administration"*

Cross reference should be made to "Special Warnings and Precautions"

Under "Special Warnings and Precautions"

"Cardiovascular effects:

Epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients older than 60 years, patients taking daily doses greater than 30mg, and patients concurrently taking QT-prolonging drugs or CYP3A4 inhibitors. Domperidone should be used at the lowest effective dose in adults and adolescents 12 years of age and older. Domperidone is contraindicated in patients with known existing prolongation of cardiac conduction intervals, particularly QTc, in patients with significant electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia), or bradycardia, or in patients with underlying cardiac diseases such as congestive heart failure due to increased risk of ventricular arrhythmia."

(iii) *Contraindications:*

- *Known hypersensitivity to domperidone or any of the excipients*
- *Prolactin-releasing pituitary tumor (prolactinoma)*
- *When stimulation of the gastric motility could be harmful e.g. in patients with gastro-intestinal haemorrhage, mechanical obstruction or perforation*
- *In patients with moderate or severe hepatic impairment*
- *In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure*
- *Co-administration with QT-prolonging drugs*
- *Co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects)*

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