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

Drug Office
Department of Health
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
香港九龍觀塘巧明街100號
Landmark East 友邦九龍大樓
20樓2002-05室
衞生署藥物辦公室

5th May 2022

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Diuretics

On 28th April 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 related to the risks of eye disorders, i.e. choroidal effusion with acute myopia and/or acute angle-closure glaucoma associated with certain diuretics including acetazolamide, chlorthalidone, hydrochlorothiazide, indapamide and metolazone by the drug regulatory authorities of Australia, Canada, 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:

"Warnings and Precautions

Ophthalmologic

Choroidal effusion, Secondary Acute Angle-Closure Glaucoma and/or Acute Myopia

Sulfonamide or sulfonamide derivative drugs can cause an idiosyncratic reaction, which may result in choroidal effusion, secondary acute angle-closure glaucoma and/or acute transient myopia. Symptoms include acute onset of decreased visual acuity, blurred vision or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue <generic name> as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

Adverse Reactions

The following adverse reactions were reported in post-marketing use: Ophthalmologic: eye disorders (secondary acute angle-closure glaucoma, acute myopia and choroidal effusion with frequency "unknown")"

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 Drug Office via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at https://www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp 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