

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

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圖文傳真

C/O Drug Office
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28th June 2021

To: Certificate holders of registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Vascular Endothelial Growth Factor (VEGF) Pathway Inhibitors

On 24th June 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 for pharmaceutical products for systemic administration containing VEGF pathway inhibitors (excluding those administered intravitreally) by the drug regulatory authorities of Australia, Canada, European Union, Singapore, United Kingdom and United States and decided that the sales pack labels and / or package inserts of such products should include the following new safety information (or equivalent):

" Special warnings and precautions for use

Aneurysms and artery dissections

The use of VEGF pathway inhibitors in patients with or without hypertension may promote the formation of aneurysms and/or artery dissections. Before initiating [Product Name / Generic Name], this risk should be carefully

considered in patients with risk factors such as hypertension or history of aneurysm.

Undesirable effects

Aneurysms and artery dissections are listed as adverse reactions under vascular disorders with frequency "not known"."

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