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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香港九龍南昌街382號
公共衞生檢測中心三樓

22nd February 2019

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Topical Oral Benzocaine Products

On 21st February 2019, 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 benzocaine products imposed by the drug regulatory authorities of the United States, European Union, Canada, Australia and Singapore, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing benzocaine for topical oral use should be updated and replaced by the following new safety information as appropriate:

"***Warnings***

Methemoglobinemia warning

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek

immediate medical attention if you or a child in your care develops:

- *pale, gray or blue colored skin (cyanosis)*
- *headache*
- *rapid heart rate*
- *shortness of breath*
- *dizziness or lightheadedness*
- *fatigue or lack of energy*

Do not use:

- *for teething*
- *in children under 2 years of age"*

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 by the Committee.

If you have any enquiries on the above issue, please contact Mr. Paul WONG at 2209 9495.

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/PW