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

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香港九龍南昌街382號
公共衞生檢測中心三樓

To: Certificate holders of
registered pharmaceutical products

05 MAY 2015

Dear Sirs / Madams,

Registered Pharmaceutical Products containing Ambroxol or Bromhexine

On 23 April 2015, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board considered the latest recommendations on ambroxol and bromhexine with regard to the risk of severe allergic reactions and severe cutaneous adverse reactions announced by some overseas drug regulatory agencies such as European Medicines Agency, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing ambroxol or bromhexine should include the following new safety information or similar meanings:

"Warning and precautions

There have been reports of hypersensitivity reactions, anaphylactic reactions, and severe skin reactions such as erythema multiforme, Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and acute generalised exanthematous pustulosis (AGEP) associated with the administration of < ambroxol/ bromhexine >. If symptoms or signs of a progressive skin rash (sometimes associated with blisters or mucosal lesions) are present, treatment should be discontinued immediately and medical advice should be sought."

"警告及注意事項

有報告顯示使用 <氨溴索〔ambroxol〕/ 溴己新〔bromhexine〕> 後，可能引致過敏反應、過敏反應綜合症和嚴重皮膚反應（例如：多形性紅斑、史蒂文斯-約瀚遜綜合症/中毒性表皮壞死松解症、和急性廣泛發疹性膿疱病）。如使用有關藥物後，出現持續變壞的皮膚紅疹症狀(有時可能引致水疱或黏膜破損)，應該立即停止療程及尋求醫生意見。"

2. You are required to review, and revise if necessary, the sales pack labels and/or package inserts of the concerned products registered by your company to comply with the above requirements.

3. Please submit the revised sales pack label(s) and/or package insert(s) within 2 months from the date of this letter for approval. Otherwise, the Committee may consider to de-register, suspend or not to renew the registration of the products that do not comply with the above requirements.

Yours faithfully,

(Clive CHAN)
Secretary
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee

c.c. 7-15/3, Product Files
CC/CC