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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

22 January 2013

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

New Labelling Information for all Botulinum Toxin Products in Canada

Your attention is drawn to Health Canada's announcement on 21 January 2013 with respect to the new labelling information for all Botulinum Toxin products.

The labelling changes are due to a risk evaluation of the active ingredients (Clostridium botulinum toxin type A and type B) within these products. Botulinum toxins are produced by different manufacturing processes, are obtained by different techniques and are derived from different Clostridium strains. As a result of these differences, these products cannot be interchanged as these changes can cause unexpected side-effects.

In order to help prevent medication errors with the use of botulinum toxin products currently available on the Canadian market, Health Canada will be requesting that all manufacturers of these products revise their product labels to reflect that each product has its own individual potency and as such, is not interchangeable with other botulinum products.

Please refer to Health Canada's website for details:

http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2013/2013_07-eng.php

In Hong Kong, there are six registered pharmaceutical products containing botulinum toxin, namely, Dysport for Inj (HK-36983), BOTOX for Inj 100 Units (HK-41906), BOTOX for Inj 200 Units (HK-60427), BTXA for Inj 50 Units (HK-51582), BTXA for Inj 100 Units (HK-49886) and SIAX Inj 100 Units (HK-56847). They are prescription-only medicines and can be indicated for the treatment of blepharospasm, hemifacial spasm and strabismus. The Department of Health will keep vigilant against any updated safety issue of the products from other overseas regulatory authorities.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(H F LEE)
for Assistant Director (Drug)