

PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

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本局檔號

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21st April 2016

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Safety Warnings for Iodine-containing Contrast Agents

On 14th April 2016, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest overseas recommendations on the rare cases of underactive thyroid in infants given iodine-containing contrast agents for medical imaging, and decided that the sales pack labels and/or package inserts of pharmaceutical products of iodine-containing contrast agents should include the following new safety warnings:

Adverse reactions

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism.

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 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 the Drug Office duty officer at 2319 8458.

Yours sincerely,



(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
KL/CC