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Dear Healthcare Professionals,



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

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Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that pharmacoepidemiological studies have shown a dose-dependent increased risk of non-melanoma skin cancer (basal cell carcinoma [BCC] and squamous cell carcinoma [SCC], including SCC lip cancer) with exposure to increasing cumulative doses of hydrochlorothiazide.

Two recent pharmacoepidemiological studies in Danish nationwide data sources (including the Danish Cancer Registry and National Prescription Registry) have shown a cumulative, dose-dependent, association between hydrochlorothiazide and non-melanoma skin cancer. The known photosensitising actions of hydrochlorothiazide could act as possible mechanism for this risk. The study authors' analyses did not find a similar association for risk of BCC or SCC and SCC lip cancer with overall or cumulative use of other diuretics and other hypertensives, including bendroflumethiazide, calcium channel blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists, and furosemide. Pedersen and colleagues reported that, assuming causality, 9 in 100 SCC cases and fewer than 1 in 100 BCC cases that were diagnosed during the study period may have been attributed to hydrochlorothiazide use. Pottegård and colleagues reported that 11 in 100 of SCC lip cancer cases occurring in the study period may have been attributed to hydrochlorothiazide use.

Based on the results of the two Danish epidemiological studies, a best estimate of the increased risk is 7.7-fold for SCC and 1.5-fold for BCC based on a length of usage of hydrochlorothiazide 12.5mg daily for 44 years or 25 mg daily for 22 years. For hypertension, products containing 25 mg of hydrochlorothiazide are indicated only if patients are not adequately controlled on lower-dose products.

The Summary of Product Characteristics and Patient Information Leaflets for all the concerned products have been updated to inform of the risk of non-melanoma skin cancer.

Healthcare professionals are advised:

- inform patients taking hydrochlorothiazide-containing products of the risk of non-melanoma skin cancer, particularly in long-term use, and advise them to regularly check for and report any new or changed skin lesions or moles.
- reconsider the use of hydrochlorothiazide in patients who have had previous skin cancer.
- examine all suspicious moles or skin lesions (potentially including histological examination of biopsies).
- advise patients to limit their exposure to sunlight and UV rays and use adequate protection when exposed to sunlight and UV rays to minimise the risk of skin cancer.

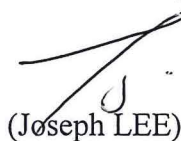
Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/hydrochlorothiazide-risk-of-non-melanoma-skin-cancer-particularly-in-long-term-use>

In Hong Kong, there are 104 registered pharmaceutical products containing hydrochlorothiazide, and all products are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to hydrochlorothiazide, but these cases are not related to skin cancer. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)