

衛生署藥物辦公室
藥物註冊及進出口管制部

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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

3 March 2014

(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

**New contraindication on the use of high dose diclofenac for more than four weeks
in selected groups of patients**

Your attention is drawn to the Health Sciences Authority's (HSA) announcement with respect to the use of high dose systemic diclofenac (one of the non-steroidal anti-inflammatory drugs (NSAIDs)) (150mg/day) for more than four weeks is contraindicated in patients with established cardiovascular (CV) disease or uncontrolled hypertension.

This regulatory decision was made following HSA's benefit-risk assessment, in consultation with its Product Vigilance Advisory Committee and several other clinical experts. The safety review was conducted in response to a growing body of scientific evidence suggesting that high doses of diclofenac used over a long duration is associated with increased CV risks.

In addition to the new contraindication, healthcare professionals are advised that if diclofenac treatment is needed, patients with established CV disease, uncontrolled hypertension or significant CV risk factors (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated only after careful consideration and at doses ≤ 100 mg daily if the treatment is for more than 4 weeks. As the CV risks of diclofenac may increase with dose and duration of exposure, diclofenac should always be prescribed at the lowest effective daily dose and for the shortest duration possible.

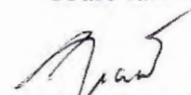
Please refer to HSA's website for details:

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/DHCP L.html

In Hong Kong, there are 162 registered pharmaceutical products (excluding external preparations) containing diclofenac. They are prescription only medicines indicated for the treatment of arthritis and many other inflammatory and/or painful conditions. The issue of NSAIDs and risk of heart problems had been mentioned in our previous letter issued on 30 September 2011. The Registration Committee of the Pharmacy Poisons Board (the Registration Committee) later decided that NSAIDs-containing products other than external preparations should include new safety warnings regarding the cardiovascular risk. In view of HSA's latest recommendation, the matter will be discussed in the meeting of the Registration Committee. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,


(Mr. Grant NG)
for Assistant Director (Drug)

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*