

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

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- 5 OCT 2015

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Safety Warnings for
Oral Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) excluding Aspirin; and
Ibuprofen for Systemic Use

In order to ensure the safe use of oral Non-Steroidal Anti-Inflammatory drugs (NSAIDs) and ibuprofen for systemic use, 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 decided at the meeting on 17 September 2015 that new safety warnings should be printed on the sales pack labels and/or package inserts of the oral NSAIDs excluding Aspirin; and products containing ibuprofen for systemic use. The affected products and examples of the new safety warnings are provided at Annexes I and II respectively.

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 at 23198458.

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
SM/CC

Annex I

List of the Affected Products

Selective COX-II NSAIDs:

Celecoxib, Etoricoxib, etc.

Non-Selective NSAIDs excluding Aspirin

Acemetacin, Carprofen, Dexketoprofen, Diclofenac, Etodolac, Flurbiprofen, Ibuprofen, Indomethacin, Ketoprofen, Ketorolac, Mefenamic Acid, Meloxicam, Naproxen, Nimesulide, Phenazone, Piroxicam, Proglumetacin, Propyphenazone, Sulindac, Tenoxicam, Tolfenamic Acid, etc.

Annex II

New Safety Warnings for:

(a) Oral NSAIDs excluding Aspirin

“Warning: In rare cases, (name of the NSAID) has been associated with serious liver injury.”

(b) Ibuprofen for Systemic Use

(I) *“Oral ibuprofen at a daily dose of 2400mg should be avoided in patients with ischemic heart disease, cerebrovascular disease, congestive heart failure or with risk factors for cardiovascular disease.”*

(II) *“Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.”*