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藥物註冊及出入口管制組
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

11 July 2007

Dear Doctor,

Safe Use of Pharmaceutical Products containing Piroxicam

Recently, the European Medicines Agency recommended restrictions on the use of pharmaceutical products containing piroxicam because of the risk of gastrointestinal side effects and serious skin reactions. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that piroxicam should no longer be used for treatment of short-term painful and inflammatory conditions. Piroxicam can still be prescribed for the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and should not be used as a first-line treatment. Topical medications containing piroxicam are not affected by these restrictions.

I wish to inform you that the Registration Committee of the Pharmacy and Poisons Board has considered the above and has decided that the recommendations of the CHMP on the use of piroxicam should be communicated to doctors. The recommendations are as follows:

a) its use in the treatment of acute painful and inflammatory conditions should be abandoned,

b) its use should be limited only to the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis,

c) it should not be used as a first-line treatment,

d) its dose should be limited to a maximum of 20mg a day,

e) it should always be used with a gastroprotective agent, such as misoprostol or a proton-pump inhibitor,

f) it should not be used in patients who are more likely to develop side effects, such as those with a history of gastro-intestinal disorders associated with bleeding, or those who have had skin reactions to other medicines, and

g) it should not be used with any other non-steroidal anti-inflammatory drug (NSAID) or an anticoagulant.

In Hong Kong, there are 48 registered pharmaceutical products containing piroxicam for oral use and 3 registered products for parenteral use. Letters are being issued to the registration certificate holders of these products to inform them to amend their product inserts accordingly.

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Link to the European Medicines Agency regarding this issue:
http://www.emea.europa.eu/pdfs/human/press/pr/26514407en.pdf

Yours faithfully,

(Y L MAK)
Secretary
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee