衞生署
藥物註冊組
香港九龍南昌街 382 號公共衞生檢測中心三樓

DEPARTMENT OF HEALTH
PHARMACEUTICALS REGISTRATION SECTION
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street,
Kowloon,
Hong Kong.

電話號碼 Tel. No.: 2319 8458
詢問處 Enquiries (852)2319 8458
傳真號碼 Faxline No. (852)2803 4962

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BY FAX

22 July 2011

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

European Medicines Agency's new recommendations on pioglitazone

Your attention is drawn to that the European Medicines Agency (EMA) has completed a review of pioglitazone-containing medicines, following concerns over the possible risk of bladder cancer. The EMA's Committee for Medicinal Products for Human Use (CHMP) concluded that, although there is a small risk of bladder cancer with pioglitazone, its benefits continue to outweigh its risks in certain patients with type 2 diabetes. However, prescribers are advised to carefully select patients and monitor response to treatment.

The CHMP recommends the prescribers not to use these medicines in patients with current or a history of bladder cancer or in patients with uninvestigated macroscopic haematuria. Risk factors for bladder cancer should be assessed before initiating pioglitazone treatment. In light of age-related risks, the balance of benefits and risks should be considered carefully both before initiating and during treatment in the elderly. Prescribers should review the treatment of patients on pioglitazone after three to six months (and regularly afterwards) to ensure that only patients who are deriving sufficient benefit continue to take it.

At present, the CHMP agreed that there is a need for further analysis. It also remains unclear as to whether it is an early effect or a risk with prolonged use/high cumulative dose. Therefore, the CHMP has asked the marketing authorisation holder to conduct a pan-European epidemiological study focusing on more robust characterisation of the risk, to inform the evidence-base for risk minimisation measures. For details, please refer to EMA's website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/07/news_detail_001311.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 24 pioglitazone-containing products registered and are prescription medicines. A letter has been issued to you on 16 June 2011 regarding the news about the risk of bladder cancer. As mentioned, the matter will be discussed in the coming meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Pharmaceutical Service under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Ms Pamela LI)
for Chief Pharmacist