衞生署
藥物註冊組
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BY FAX

23 May 2011

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

Dear Dr. LIANG,

European Medicines Agency Recommends Suspension Of Oral Buflomedil-containing Medicines

Your attention is drawn to the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) recommended that the supply of oral buflomedil-containing medicines be suspended in all European Union (EU) Member States where it is currently authorised. This is an interim recommendation pending the finalisation of the continuing review of the benefits and risks of buflomedil solution for injection. The CHMP will adopt an opinion at the end of the full review.

Buflomedil, a vasoactive agent, is used to treat the symptoms of peripheral arterial occlusive disease (PAOD). This is a condition where the body's large arteries become obstructed causing symptoms such as pain and weakness, particularly in the legs. Buflomedil is used in patients with stage II PAOD, who experience severe pain when walking even relatively short distances.

The CHMP concluded that serious and sometimes fatal neurological and cardiac side effects, mainly related to accidental or intentional overdose, continued to occur, despite measures put in place by regulatory authorities previously to reduce the risk of overdosing. The CHMP also noted that the medicine had only been shown to have a limited benefit for patients, measured in terms of walking distance, and the studies assessed had a number of weaknesses. The CHMP concluded that the benefits of buflomedil-containing medicines in the form of tablets or an oral solution do not outweigh their risks, and recommended that the supply of these medicines should be suspended throughout the EU. For detail, please refer to EMA's website : -
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/05/news_detail_001260.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

Situation in Hong Kong: there is a product containing buflomedil, namely Bumedin Tablet 150mg (HK-41375) registered by Anderson International Company Limited. Any updated progress of EMA and actions from other health authorities will be kept in view. The issue 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 drug 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