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本署檔號 OUR REF.: DH PS PRIE/7-30/15
(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

23 May 2011

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

Dear Dr. LIANG,

Updated Safety Information on Use of Celecoxib in Familial Adenomatous Polyposis

Your attention is drawn to the European Medicines Agency's conclusion on the use of celecoxib in familial adenomatous polyposis (FAP). The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has finalised its review of the use of the COX-2 inhibitor celecoxib in the reduction of the number of adenomatous intestinal polyps in FAP, and concluded that existing evidence of safety and efficacy does not support the use of celecoxib in FAP patients. Celecoxib is not to be used off-label following Onsenal withdrawal.

Celecoxib-containing products are currently authorised in the European Union for the treatment of the symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. This review was initiated because of concerns that celecoxib may be used off-label in the FAP indication following the withdrawal of Onsenal.

The CHMP looked at the available data on the use of celecoxib in FAP patients. This included the results from the main study that supported the marketing authorisation for Onsenal, an ongoing study with celecoxib, post-marketing safety data and data from the published literature.

The CHMP concluded that the benefit of celecoxib in FAP patients had not been sufficiently demonstrated and did not outweigh the increased risk of cardiovascular and gastrointestinal side effects, which would result from high dose and long-term treatment used in FAP patients. For detail, please refer to the EMA's website : -
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/05/news_detail_001259.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 12 registered products containing celecoxib and they are all prescription only medicines. The indication for FAP is no longer an approved indication in Hong Kong.

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