衞生署
藥物註冊組
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Dear Healthcare Professionals,

Alert on use of Celecoxib for Familial Adenomatous Polyposis

Your attention is drawn to the withdrawal of the marketing authorisation for Onsenal (celecoxib) in the European Union.

Onsenal (celecoxib) is marketed in European Union for the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis (FAP), as an adjunct to surgery and further endoscopic surveillance. In 2003, the European Commission (EC) issued the marketing authorisation of Onsenal under exceptional circumstances with specific obligation of the applicant to provide further data on its efficacy and safety.

Onsenal was undergoing the reassessment by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The CHMP requested supplementary information to be provided in order to confirm that the benefits associated with the use of Onsenal in the treatment of FAP still outweigh its risks. The marketing authorisation holder, Pfizer Limited notified EC its decision to voluntarily withdraw the marketing authorisation for Onsenal as the company was not able to provide the efficacy data, as a result of slow enrolment in an ongoing clinical trial. The EC then issued a decision to withdraw the marketing authorisation for Onsenal. For details, please visit EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/04/news_detail_001236.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, Onsenal Cap 400mg (HK53007) was once registered by Pfizer Corporation Hong Kong Ltd. but it has never been marketed locally. However, Celebrex Cap (100mg-HK44730; 200mg-HK44731 & 400mg-HK52866), another prescription medicine containing celecoxib is available in Hong Kong. Celebrex was indicated for osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute pain, primary dysmenorrheal and FAP; and its package insert is being updated to remove the indication for FAP.

Please 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 faithfully,

(Ms Pamela LI)
for Chief Pharmacist