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BY FAX

25 March 2013

Dr. Donald LI
President
Hong Kong Academy of Medicine
Fax: 2505 5577

Dear Dr. LI,

Recommendation on restricting the use of cilostazol-containing medicines

Your attention is drawn to that the European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) recommended the use of cilostazol-containing medicines in the treatment of intermittent claudication (i.e. a condition where poor blood supply to the leg muscles causes pain and affects the ability to walk) be restricted with a range of new measures aimed at targeting a patient population in which there are clinical benefits, and at the same time minimising important risks.

The recommendations followed a review of current evidence which indicated that the modest benefits of these medicines, i.e. their ability to increase the distance patients are able to walk, are only greater than their risks, in particular the risks of side effects affecting the heart or serious bleeding, in a limited subgroup of patients.

The CHMP recommended that cilostazol should only be used in patients whose symptoms have not improved despite prior lifestyle changes such as exercise, healthy diet and stopping smoking. In addition, cilostazol-containing medicines should not be used in patients who have suffered severe tachyarrhythmia, or recent unstable angina, heart attack or bypass surgery, or who take two or more antiplatelet or anticoagulant medicines such as aspirin and clopidogrel. Doctors were recommended to review their patients at their next routine appointment and assess the continued suitability of cilostazol treatment.

The CHMP considered that although on average the efficacy of cilostazol is modest, there is a small group of patients in whom it is of clinical relevance, not least in helping them to begin exercise programmes. Although suspected adverse drug reaction reports have raised some safety concerns, these have not been substantiated in the clinical trial data, and it remains possible to exclude high-risk patients in clinical practice. Detailed recommendations for patients and healthcare professional are available at the link below:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/03/news_detail_001746.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are three pharmaceutical products containing cilostazol registered under the name of Pletaal (HK-47373, HK-51136 and HK-61321). The products are registered by Otsuka Pharmaceutical (HK) Ltd (Otsuka) and are prescription-only medicines. The registered indications include the treatment of ischemic symptoms. The Department of Health (DH) has contacted Otsuka for updates and details of the situation, and will keep vigilant on the issue.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office

Yours faithfully,

(Ms. Pamela LI)
for Assistant Director (Drug)

DH 1110BA

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