

衛生署藥物辦公室  
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Dr. LIANG,

**European Union: European Medicines Agency starts review of Tredaptive, Pelzont and Trevaclyn**

Your attention is drawn to that the European Medicines Agency has started a review of the safety and efficacy of Tredaptive, Pelzont and Trevaclyn, identical medicines that are used to treat adults with dyslipidaemia, particularly combined mixed dyslipidaemia and primary hypercholesterolaemia.

The review was triggered because the Agency was informed by the pharmaceutical company Merck, Sharp & Dohme of the preliminary results of a large, long-term study comparing the clinical effects of adding these medicines to statins with statin treatment alone. The study raises questions about the efficacy of the medicine when added to statins, as this did not reduce the risk of major vascular events compared with statin therapy alone. In addition, in the preliminary results a higher frequency of non-fatal but serious side effects was seen in patients taking the medicines than in patients only taking statins.

The Agency's Pharmacovigilance Risk Assessment Committee will assess the data and make a recommendation to the Committee on Medicinal Products for Human Use, which will issue an opinion on the regulatory action required. An opinion is expected in January 2013.

While the review is ongoing, the Agency recommended that no new patients should be started on treatment with these medicines or enrolled in clinical trials involving these medicines, pending the outcome of the Agency's assessment; and patients currently using these medicines should not stop their treatment and should speak to their doctors at their next appointment for any questions.

Please refer to MHRA's website for details:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2012/12/news\\_detail\\_001686.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001686.jsp&mid=WC0b01ac058004d5c1)

In Hong Kong, Tredaptive tablet is registered by Merck Sharp & Dohme (Asia) Ltd and is prescription-only medicine while Pelzont and Trevaclyn are not registered pharmaceutical products. Tredaptive contains nicotinic acid (also known as niacin or vitamin B3) and laropiprant. It is indicated

primary hypercholesterolaemia. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

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: 3904 1225 or email: [adr@dh.gov.hk](mailto:adr@dh.gov.hk)). For details, please refer to the website at Drug Office under "ADR reporting": <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 sincerely,



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

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