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藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

FDA Drug Safety Communication: Important safety label changes to cholesterol-lowering statin drugs

Your attention is drawn to that the U.S. Food and Drug Administration (FDA) announced an approved important safety label changes for the class of cholesterol-lowering drugs known as statins. These changes were made to provide more information for the safe and effective use of statins and are based on FDA's comprehensive review of the statin class of drugs. The changes include the following:

- Monitoring Liver Enzymes: labels have been revised to remove the need for routine periodic monitoring of liver enzymes in patients taking statins. The labels now recommend that liver enzyme tests should be performed before starting statin therapy and as clinically indicated thereafter. FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing serious liver injury.

- Adverse Event Information: information about the potential for generally non-serious and reversible cognitive side effects (memory loss, confusion, etc.) and reports of increased blood sugar and glycosylated hemoglobin (HbA1c) levels has been added to the statin labels. FDA continues to believe that the cardiovascular benefits of statins outweigh these small increased risks.

- Drug Interactions: the lovastatin label has been extensively updated with new contraindications (situations when the drug should not be used) and dose limitations when it is taken with certain medicines that can increase the risk for muscle injury.

In the United States, healthcare professionals should refer to the drug labels for the latest recommendations for prescribing statins. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment, therapy should be interrupted. If an alternate etiology is not found, the statin should not be restarted. For details, please refer to FDA's website:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm293670.htm

In Hong Kong, there are a total of 241 registered pharmaceutical products which belong to the class of statins, among them 11 products contain lovastatin. All are prescription-only medicines. In view of FDA's recommendation, the issue will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the following website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html.

Yours sincerely,

(Ms Pamela LI)
for AD(D)