Dear Dr. LIANG,

**TGA: Simvastatin: new contraindications, precautions and dosage recommendations**

Your attention is drawn to that the Therapeutic Goods Administration (TGA) is advising health professionals to limit the prescribing of high dose (80 mg/day) simvastatin and to be aware of new contraindications and precautions for the use of simvastatin with other medicines. Simvastatin is used to control elevated cholesterol, or hypercholesterolemia.

The TGA recommends that 80mg/day simvastatin should only be used in patients at a high risk of cardiovascular complications who have not achieved their treatment goals on lower doses. Patients on high dose simvastatin and those taking certain other medicines have an increased risk of developing myopathy (muscle weakness) and, more rarely, rhabdomyolysis. Concomitant administration of simvastatin with the following medicines is now contraindicated: gemfibrozil, cyclosporine, danazol and potent CYP3A4 inhibitors such as itraconazole, ketoconazole, posaconazole, erythromycin, clarithromycin, telithromycin, nefazodone and HIV protease inhibitors. Specific precautions (such as lower recommended simvastatin doses) now exist for patients taking the following medicines: moderate inhibitors of CYP3A4, amiodarone, the calcium channel blockers verapamil, diltiazem and amlodipine, fibrates other than gemfibrozil, niacin (≥1g/day) and colchicine.


In Hong Kong, there are 128 simvastatin-containing products registered and all are prescription-only drugs. Similar news has been released by the US FDA. However, the concomitant use with niacin (≥1g/day) and colchicine has not been regarded as contraindication for simvastatin at that time. After the discussion by Registration Committee of the Pharmacy and Poisons Board, warnings have been included in the sales packs for products containing simvastatin. In view of TGA’s recommendation, the issue will be further discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: [http://www.drugoffice.gov.hk](http://www.drugoffice.gov.hk) at Drug Office under “Reporting an Adverse Drug Reaction”.

Yours sincerely,

(Ms Pamela LI)
for AD(D)

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