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Advisory

2005-77

July 12, 2005

For immediate release

Health Canada advises consumers about important safety information on statins

OTTAWA - Health Canada is advising Canadians about important safety information for all cholesterol-lowering drugs known as statins. These medications include Lipitor (atorvastatin), Zocor (simvastatin), Mevacor (lovastatin), Lescol and Lescol XL (fluvastatin), Pravachol (pravastatin) and Crestor (rosuvastatin).

Some patients may have pre-existing medical conditions which might cause them to have a greater risk of developing muscle-related problems, including a serious condition called rhabdomyolysis (serious muscle damage), if patients are using *Statin* medications. Rare reports of rhabdomyolysis have been seen worldwide and in Canada with the use of these drugs.

Health Canada had requested that all manufacturers of these drugs include a warning and description of this risk in the safety information sheets for each drug. The updates to the safety information sheet are now complete.

Before taking a statin, patients should tell their doctor or pharmacist if they:

- are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed;
- have thyroid problems;
- regularly drink three or more alcoholic drinks daily;
- are taking other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate) or niacin;
- are taking other medications, including prescription, non-prescription and natural health products, as drug interactions are possible;
- have a family history of muscular disorders;
- had any past problems with the muscles (pain, tenderness), after using a statin;
- have kidney or liver problems;
- have diabetes;
- have undergone surgery or other tissue injury;
- do excessive physical exercise.

Patients are advised to contact their physician promptly if they experience any of the following while on statin therapy:

- muscle pain they cannot explain;
- muscle tenderness or muscle weakness;
- generalized weakness, especially if they do not feel well (i.e. fever or fatigue);