



October 8, 2010

Apotex to stop marketing Apo-Sibutramine (Obesity Medicine) in Canada

After discussion with Health Canada, Apotex is voluntarily withdrawing Apo-Sibutramine from the Canadian market. Health Canada's recommendation came in light of data from the Sibutramine Cardiovascular OUTcomes (SCOUT) trial, a large study that suggested an increased risk of serious cardiovascular events associated with sibutramine use in patients with heart problems. The purpose of the study was to determine a link between long-term sibutramine use and the risk of cardiovascular events in patients with pre-existing cardiovascular disease, or who were at risk of heart-related adverse events. Nearly 10,000 overweight and obese subjects aged 55 years and older were enrolled in the trial for up to six years.

It is important to note that sibutramine has not been recommended for use in patients with existing cardiovascular disease. Health Canada has communicated in the past on the risk of cardiovascular events in patients with heart problems and on the importance of prescribing sibutramine as directed in the approved Product Monograph.

Despite these previous risk mitigation measures, there continues to be concern of an increased risk of heart-related adverse events, particularly as people at risk of cardiovascular disease may not have symptoms. In light of this concern, and the accumulating scientific evidence on the safety and efficacy of sibutramine, it was concluded by Health Canada that the benefit-risk ratio has changed.

It is recommended that patients taking Apo-Sibutramine see their physician to discuss alternatives for weight loss.