

Health

Public Health and Primary Health Care Division Communicable Disease Control 4th Floor, 300 Carlton St, Winnipeg, MB R3B 3M9 T 204 788-6721 F 204 948-2040 www.manitoba.ca

October 27, 2012

Dear Health Care Provider:

On October 26th, as a precautionary step, Health Canada asked Novartis to suspend distribution of the Agriflu and Fluad influenza vaccines in Canada until a full review of the situation is completed. Novartis has agreed. The Public Health Agency of Canada is also recommending that health care professionals in possession of these vaccines refrain from using them until the review is complete.

This action was triggered by the finding of white precipitate or clumping in Novartis influenza vaccines distributed in Europe. This is a common phenomenon in vaccines and Health Canada has previously seen such particles and observed no impact on vaccine safety or effectiveness. There have been no reports of serious or unexpected adverse events related to these vaccines in Manitoba, Canada, or Europe.

The majority (approximately 99% of vaccine shipped to date in Manitoba) has been GSK produced Fluviral and is not impacted by suspension above. However, a small quantity (approximately 1% of vaccine shipped to date in Manitoba) is Novartis produced Agriflu. Fluad is currently not used by Manitoba's influenza vaccination program.

If you have received Agriflu for your patients, please mark it as do not use, maintain cold chain at 2-8 degrees Celsius and await further direction from MB Health concerning its use.

If you have administered Agriflu to your patients please advise them that no safety or effectiveness issues are expected with this products use.

Sincerely,

Original approved by Tim Hilderman, MD

Tim Hilderman, MD Medical Officer of Health Communicable Disease Control

