From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, July 06, 2017 2:43 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Novopen Echo Insulin Delivery Device by Novo Nordisk: Recall - May Crack or Break If Exposed To Certain Chemicals

ISSUE: Novo Nordisk is initiating a recall of insulin cartridge holders used in a small number of NovoPen Echo batches because they may crack or break if exposed to certain chemicals, like certain cleaning agents. Using a device with a cracked/broken cartridge holder may result in the device delivering a reduced dose of insulin which could potentially lead to high blood sugar.

Novo Nordisk has received numerous complaints of damaged cartridge holders and has received some reports of adverse events to date.

The affected batches were distributed between 8/1/2016 – 6/22/2017 to distributors, sales representatives and replacement programs for further distribution to pharmacies, healthcare providers and patients nationwide.

BACKGROUND: The warning signs of high blood sugar (also known as hyperglycemia) typically appear gradually and might include flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea or vomiting).

RECOMMENDATION: Patients using an affected pen may want to check their blood sugar level more frequently until receiving a new cartridge holder. Patients should contact their health care provider if they believe they're experiencing hyperglycemia. For questions specific to the recall, please call 1-855-419-8827.

Novo Nordisk is notifying distributors, pharmacies, healthcare professionals and patients by mail and is arranging for product replacement. See the press release for additional information.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm565955.htm