Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, December 03, 2015 10:20 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: OmniPod Insulin Management System by Insulet: Field Safety Notification - Reported Cases of Needle Mechanism Deployment Failure or Delay

ISSUE: On November 2, 2015, Insulet Corporation initiated a lot-specific voluntary Field Safety Notification (Notification) for 15 lots of the OmniPod (Pod) which were distributed in the U.S. and three lots which were distributed internationally. This Notification is due to a slight increase in the reported cases in which the Pod's needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. In the event a needle mechanism fails to deploy, the needle will not be inserted and insulin delivery will not begin. The interruption of insulin delivery may cause elevated blood glucose (hyperglycemia), which, if left untreated, can result in diabetic ketoacidosis (DKA).

The affected Pod lots have resulted in 66 Medical Device Reports, of which three required medical intervention. See the Press Release for a listing of affected product lots.

BACKGROUND: The reported incidence of this product issue in the affected lots is approximately 1%-2%. Once this issue was recognized, the Company corrected the manufacturing process and implemented additional inspection steps. This Notification does not affect the OmniPod Personal Diabetes Manager (PDM).

RECOMMENDATION: Insulet has notified its distributors and customers by email, FedEx, and phone calls. Consumers who have Pods from the affected lots should ensure the needle mechanism has deployed properly, and may contact Insulet Customer Care via telephone at 1-855-407-3729 at any time.

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

[12/01/2015 - Press Release - Insulet Corp.]