To: Z029337 (5064445113) HEAD NURSE; NEW MARYLAND ELEMENTARY SCHOOL (P8527B)
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SANOFI

October 28th, 2015

Voluntary Nationwide Recall of Allerject® Due to Potential Inaccurate Dosage Delivery

Dear Educator,

On October 28th, 2015 Sanofi Canada announced that it is recalling all Allerject® (epinephrine injection, USP). The voluntary recall involves all Allerject currently on the market and includes both the 0.15 mg/0.15 mL and 0.3 mg/0.3 mL strengths for hospitals, retailers and consumers. The products have been found to potentially have inaccurate dosage delivery. If a patient who is experiencing a serious allergic reaction (i.e. anaphylaxis) did not receive the intended dose, there could be significant health consequences, including death because anaphylaxis is a potentially life-threatening condition.

As of October 26, 2015, Sanofi US and Canada have received 26 reports of suspected device malfunctions from an estimated 2,784,000 units distributed in North America.

Specifically, in Canada, 9 suspected device malfunctions were reported out of an estimated 492,000 units distributed. None of these device malfunction reports have been confirmed. In these reports, patients have described symptoms of the underlying hypersensitivity reaction. No fatal outcomes have been reported among these cases.

Allerject (epinephrine injection USP) is used to treat life-threatening allergic reactions (anaphylaxis) in people who are at risk for or have a history of these reactions. All Allerject units are being recalled.

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Sanofi Canada is proactively communicating with wholesalers, pharmacists, patients and caregivers, patient associations, and hospitals to inform them of this precautionary voluntary recall and how to proceed.

Sanofi Canada is actively working with suppliers of alternative epinephrine auto-injectors to have full stock available in Canada as soon as possible.

Canadian customers are asked immediately return the product to their local pharmacy or point of purchase to obtain an alternative epinephrine auto-injector. In the absence of availability of an alternative epinephrine auto-injector, customers are instructed to retain their Allerject device until an alternative auto-injector is available.

If customers are unable to obtain supplies of alternative epinephrine auto-injectors, and in the event of a life-threatening allergic reaction (anaphylaxis), patients who do not have a replacement product should use their Allerject device, call 911 immediately and seek medical services, in accordance with current product labelling.

Sanofi Canada is committed to patient safety and the quality of Allerject, and will continue to work closely with our partners and regulatory authorities to resolve this issue in a timely manner.

If you have any questions or concerns regarding this voluntary product recall, please contact the Allerject Call Centre at 1-855-405-4321

Any adverse events that may be related to the use of these products should be reported either to:

Sanofi Canada 1-855-405-4321

Health Canada 1-866-234-2345

MedEffect Canada website:

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

This recall is being conducted with the knowledge of Health Canada.

Sincerely,

Tracey Ramsay,
Vice-President Hospital, Specialty and Consumer Health, Sanofi Canada