SANOFI

October 28, 2015

Notice – Voluntary Product Recall Type 1 Due to Potential Inaccurate Dosage Delivery

Dear Health Care Professional,

Sanofi-aventis Canada Inc. (Sanofi Canada) is taking the precautionary measure of issuing a voluntary Type I recall of all epinephrine auto-injectors marketed as Allerject® (epinephrine injection, USP) in Canada due to potential inaccurate dosage delivery. The voluntary recall involves all Allerject currently on the market and includes both the 0.15mg/0.15mL and 0.30mg/0.3mL strengths. 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 life threatening condition.

As of October, 2015, Sanofi US and Canada have received 26 report 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 outcome has been reported among these cases.

Please note that Sanofi Canada, in addition to contacting Health Care Professionals will also be contacting retail pharmacists, emergency rooms, hospitals and stakeholders involved in the treatment of anaphylaxis across Canada. The public will also be informed of this voluntary recall.

Please ensure that any of your patients who may be in possession of an Allerject auto-injector are made aware of the recall. Patients are asked to immediately return the product to their local pharmacy to obtain an alternate epinephrine auto-injector. In the absence of availability of an alternate epinephrine auto-injector, patients are instructed to retain their Allerject device until an alternate auto-injector is available.

In light of the need to manage supply associated with this recall, we are asking customers and pharmacists to limit the replacement of Allerject to one unit, or the

appropriate number of, units as instructed by your health care professional until full alternative stock is available.

If patients 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 emergency medical services, in accordance with current product labeling.

Sanofi Canada is committed to the 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. This voluntary recall is conducted with the knowledge of Health Canada.

We regret any inconvenience that this recall may cause. If you have any questions or concerns regarding this voluntary product recall, please contact the Allerject Call Center at 1-855-405-4321, or if your question is specific to the logistics of the return, please contact Sanofi Customer Service at 1-800-265-7927.

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

Sanofi Canada
Phone: 1-855-405-4321

Health Canada
Phone: 1-866-234-2345

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

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<table>
<tr><th colspan="2">PRODUCT IDENTIFICATION
IDENTIFICATION DU PRODUIT</th></tr>
<tr><td colspan="2">Name / Nom:
Allerject 0,15 mg / 0,15 mL epinephrine injection</td></tr>
<tr><td rowspan="2">UPC/DIN
CUP/NIM</td><td>ENG. /
ANG.: 065914112164 / 02382059</td></tr>
<tr><td>FR. / FR.: 065914112171 / 02382059</td></tr>
<tr><td colspan="2">Name / Nom:
Allerject 0,3 mg / 0,3 mL epinephrine injection</td></tr>
<tr><td rowspan="2">UPC/DIN
CUP/NIM</td><td>ENG. /
ANG.: 065914112188 / 02382067</td></tr>
<tr><td>FR. / FR.: 065914112195 / 02382067</td></tr>
<tr><td colspan="2">Lot(s): All lots / Tous les lots.</td></tr>
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Sincerely,

Franca Mancino, Sanofi Canada
Vice-President Medical and Regulatory Affairs