Pfizer Canada Voluntarily Recalls One Lot of EpiPen® 0.3 mg and One Lot of EpiPen® Jr 0.15 mg (epinephrine) Auto-Injectors

KIRKLAND – March 31, 2017 – Pfizer Canada Inc., the Canadian distributor of EpiPen® (epinephrine) Auto-Injector, today announced a voluntary recall in consultation with Health Canada of one lot of EpiPen 0.3 mg (epinephrine) and one lot of EpiPen Jr 0.15 mg (epinephrine) Auto-Injectors distributed in Canada.

In Canada, the recall impacts one lot (5GU763) of the 0.3 mg strength of EpiPen Auto-Injector expiring in May 2017 and one lot (5GR765) of the 0.15 mg strength of EpiPen Jr Auto-Injector expiring in March 2017.

Photo of EpiPen 0.3 mg:
The recalled products were distributed by Pfizer Canada from January to March 2016.

Photo of EpiPen Jr 0.15 mg:
The recalled products were distributed by Pfizer Canada from November 2015 to February 2016.

This voluntary recall is being conducted as a result of the receipt of two previously disclosed reports outside of Canada of failure to activate the device due to a potential defect in a supplier component. The potential defect could make the device difficult to activate in an emergency (failure to activate or increased force needed to activate) and have significant health consequences for a patient experiencing a life-threatening allergic reaction (anaphylaxis). The incidence of the defect is extremely rare and testing and analysis across the potentially impacted lots has not identified any units with a defect. However, the recall is being conducted in Canada out of an abundance of caution.

Return Process:
Pfizer Canada is committed to replacing recalled devices at no cost. Patients, healthcare professionals, wholesalers and pharmacists are being notified. Information is available on Pfizer.ca, Pfizer Canada Facebook page or EpiPen Canada Facebook page.

Patients should keep their existing product until their replacement product can be secured.

Patients will receive an EpiPen Auto-Injector at their pharmacy as a replacement based on product availability. We are expecting additional stock to become available to meet demand in the coming weeks.

Consumers with questions regarding this recall can contact Pfizer Medical Information at 1-800-463-6001 between 9:00 a.m. and 5:00 p.m. EST.

Adverse reactions or quality problems experienced with the use of this product may be reported to 1-866-723-7111 or by fax at 1-855-242-5652. Reports can be made directly to Health Canada as well through the Canada Vigilance Program at 1-866-234-2345.

For more information, please contact:

Pfizer Canada Corporate Affairs
1-866-9Pfizer (1 866 973-4937)
CorporateAffairsCanada@pfizer.com

Important Safety Information

EpiPen® (epinephrine) Auto-Injectors are indicated for the emergency treatment of anaphylactic reactions in patients who are determined by a physician to be at increased risk for anaphylaxis. EpiPen® (epinephrine) Auto-Injectors are designed as emergency supportive therapy only. After administration, patients should seek medical attention immediately or go to the nearest emergency room. This product may not be right for you, always read and follow the label.