

**DRUG RECALL  
URGENT**



Pfizer Canada Inc.  
17300 Trans-Canada Highway  
Kirkland, Quebec H9J 2M5

**Date:** March 31, 2017

**Subject: EPIPEN® 0.3MG & EPIPEN® JR. 0.15MG AUTO-INJECTOR**  
**DIN 00509558 & 00578657**  
**LOT# 5GU763 & 5GR765**  
**EXP.: 05/2017 & 03/2017**

Pfizer Canada is voluntarily recalling EpiPen 0.3mg Auto-Injector lot 5GU763, with expiry 05/2017 and EpiPen Jr. 0.15mg Auto-Injector lot 5GR765 with expiry 03/2017. These lots were distributed in Canada from November 2015 to March 2016.

The classification of this recall is Type I: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death

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.

**Please stop sale and distribution of these lots immediately. The return and replacement process will be sent to Canadian pharmacies shortly.**

Please conduct an assessment of inventory and immediately send the attached completed product recall return form by fax to 1-888-780-4268, even if you do not have any recalled stock on hand. In this case, check the box to this effect on the form. Your response is vital to Pfizer Canada's ability to monitor the effectiveness of this voluntary recall. Health Canada has been contacted concerning this recall. Your immediate attention to the above instructions is required. Please respond to this notification by April 7, 2017, **whether you have product or not**.

**Wholesalers: please forward this notification to all of your customers.**

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that may have been caused by this action. If you have an inquiry of a medical nature related to EpiPen, please contact our Medical Information Group at 1-800-463-6001. For questions relating to the return process, please contact our Customer Service team at 1-800-387-4974.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Frohloff".

Melissa Frohloff  
Team Leader, Quality (AQO)

Enclosure



**URGENT - PRODUCT RECALL RETURN FORM**

**EpiPen® 0.3mg & EpiPen® Jr. 0.15mg Auto-Injector**

**Return by fax to PTM at: 1-888-780-4268 (You must return form whether you have inventory of these lots or not)**

**PLEASE INDICATE BELOW ALL REMAINING VIALS YOU HAVE LEFT IN INVENTORY OF THE RECALLED LOTS.**

DIN	PRODUCT CODE	PRODUCT DESCRIPTION	SIZE	UPC	LOT #	EXPIRY DATE	FIRST SALE OF LOT	# OF VIALS RETURNED
00509558	00121	EpiPen 0.3mg	1 unit	625813 001213	5GU763	05/2017	Jan 2016	
00578657	00111	EpiPen Jr. 0.15mg	1 unit	625813 001114	5GR765	03/2017	Nov 2015	

We do not have any stock of the above Lots

**PLEASE COMPLETE THE FORM AND FAX IT WITHOUT DELAY.**

<b>Customer Name:</b>		
<b>Street Address:</b>		
<b>City:</b>		
<b>Province:</b>		
<b>Postal Code:</b>		
<b>Name of Authorised Person</b>	<b>Signature</b>	<b>Date</b>

Please return all units of product identified above as well as a copy of this form by Purolator Collect (7983131) to the address below and include the number PC033117 on the waybill. Wholesalers, pharmacies and hospitals will be credited by Pfizer Canada at the current provincial list price.

Med-Turn International Inc (Inmar Healthcare Network)  
50 Dynamic Drive  
Toronto, ON,  
M1V 2W2, Canada