Pfizer Canada Inc.
C.P. 800 / P.O. Box 800
Pointe-Claire / Dorval, Québec H9R 4V2

September 28, 2018

SUBJECT: Important Safety Information on EpiPen® and EpiPen Jr® auto-injectors: A very small number of EpiPen® and EpiPen Jr® auto-injectors may stick in their carrier tube, delaying or potentially preventing emergency treatment. Consumers need to check their device now to confirm that it can be removed from the carrier tube with ease.

Dear Healthcare Professionals,

ISSUE

Pfizer Canada has advised Health Canada that, in a very small number of cases, some EpiPen® (0.3 mg) and EpiPen Jr® (0.15 mg) auto-injector devices may not slide out of their carrier tube easily, or potentially at all, which could delay or potentially prevent emergency treatment. Delayed or no treatment could lead to worsened patient outcomes, including possibly death. The estimated number of EpiPen® or EpiPen Jr® auto-injectors which may have a delay in release from the carrier tube is 1 auto-injector out of every 14,286 (0.007%).

In a very small number of cases, labels were not fully adhered to the surface of the auto-injector such that the device label may become stuck to the inside of the carrier tube. Therefore, the device may not slide out of the carrier tube as easily as expected. The issue is with the device label, and not with the device itself or the drug it delivers, adrenaline (epinephrine).

EpiPen® and EpiPen Jr® are used to deliver an emergency treatment of adrenaline (epinephrine) to patients who are at risk or have a history of life-threatening allergic reactions (anaphylaxis).

Health Canada is issuing a public advisory providing similar guidance to consumers.

WHO IS AFFECTED

- Patients and caregivers who have the affected product
- Health care providers dispensing or administering the affected product

AFFECTED PRODUCT

- EpiPen® (0.3 mg) (DIN 00509558) products expiring between April 2018 and October 2019.
- EpiPen Jr® (0.15 mg) (DIN 00578657) products expiring between April 2018 and October 2019.

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Information for Healthcare Professionals and Consumers

Information for Healthcare Professionals
Before dispensing or administering the EpiPen® or EpiPen Jr® Auto-Injectors expiring between April 2018 and October 2019, flip open the cap of the carrier tube and ensure that the auto-injector easily slides out of the carrier tube. The detailed directions, including pictures of the auto-injector, are found in Appendix 1 for Health Care Professionals.

Information for consumers
If the EpiPen® or EpiPen Jr® Auto-Injector expires between April 2018 and October 2019, consumers should check their device now by flipping open the cap of the carrier tube and ensuring that the auto-injector easily slides out of the carrier tube. The detailed directions, including pictures of the auto-injector, are found in Appendix 2 for Consumers.

Information for pharmacists
When a consumer returns an affected unit which does not easily slide out of the carrier tube, please follow the process below:

- Check the unit as per the instructions in Appendix 1.
- Replace the affected EpiPen® 0.3 mg and/or EpiPen Jr® 0.15 mg for the consumer at no charge.
- Put aside the affected EpiPen® units.
- Prepare a weekly consolidation of returns by filling out the form and return (collect) through Purolator to MedTurn/Inmar (Purolator 7983131) (Form attached)

Your primary wholesaler will credit you for the units that you have returned at the current list price.

REPORT HEALTH OR SAFETY CONCERNS
Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving EpiPen® or EpiPen Jr® should be reported to Pfizer Canada Inc. or Health Canada.

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Pfizer Canada Inc. Contact Information
17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5

Telephone: If you have an inquiry of a medical nature related to EpiPen® or EpiPen Jr®, please contact our Medical Information Group at 1-800-463-6001 (Monday – Friday 9AM-5PM). For all other inquiries, please contact our Customer Service Group at 1-800-387-4974.

To report an adverse event (or suspected side-effect) experienced with a Pfizer medication (prescription, non-prescription or a vaccine) please contact Pfizer at 1-866-723-7111 or by fax at 1-855-242-5652.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

Sincerely,

DocuSigned by:
D62C6DFD49824FC...

Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada Inc.

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Appendix 1: Special Instructions for HEALTHCARE PROFESSIONALS: Verifying EpiPen® Auto-Injectors for Ease of Removal from Carrier Tube

Before dispensing or administering EpiPen® or EpiPen Jr® auto-Injectors expiring between April 2018 and October 2019, open the carton and remove the carrier tube containing the auto-injector from the carton. Leave the package insert inside the carton.

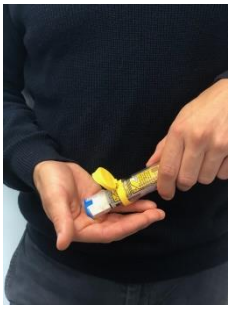
1. Check the expiry date.

2. Per the Instructions for Use, flip open the cap of the carrier tube. The carrier tube caps are:
   a. yellow for EpiPen® or Epinephrine 0.3 mg, and
   b. green for EpiPen Jr® or Epinephrine 0.15 mg.

3. Tip the carrier tube and verify that the auto-injector readily slides out of the tube. Visually inspect the auto-injector to make sure the device label has no unglued edges that may catch on the tube.

   Do *NOT* remove the blue safety release from the auto-injector. The blue safety release should be kept on the auto-injector until the time of use.

   Do *NOT* attempt to remove or re-attach the labels under any circumstances.



4. Once you have confirmed that the device slides out easily and there are no device label unglued edges, return the EpiPen® into its carrier tube and close the carrier tube flip cap. The auto-injector may be dispensed and administered.

5. If there are device label unglued edges *OR* if an auto-injector does not readily slide out of the carrier tube, the auto-injectors must *NOT* be dispensed.

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Appendix 2: Special Instructions for CONSUMERS
Verifying EpiPen® Auto-Injectors for Ease of Removal from Carrier Tube

In a non-emergency situation, follow these instructions to verify that your EpiPen® or EpiPen Jr® auto-injector slides easily from the carrier tube.

1. Check the expiry date. This issue may affect EpiPen® auto-injectors in Canada expiring between April 2018 and October 2019.

2. Per the Instructions for Use, flip open the cap of the carrier tube. The carrier tube caps are:
    a. yellow for EpiPen® or Epinephrine 0.3 mg, and
    b. green for EpiPen Jr® or Epinephrine 0.15 mg.

3. Tip the carrier tube and verify that the auto-injector slides easily from the tube. Visually inspect the auto-injector to make sure the device label has no unglued edges that may catch on the tube.

    Do ***NOT*** remove the blue safety release from the auto-injector. The blue safety release should be kept on until time of use.

    Do ***NOT*** attempt to remove or re-attach your labels under any circumstances.

4. Once you have confirmed that your device slides out easily and there are no device label unglued edges, return the EpiPen® into its carrier tube and close the carrier tube flip cap. The auto-injector may be used.

    Always keep your auto-injector in the carrier tube to protect it from damage.

5. If your device sticks or does not slide out easily from its tube, or the device label has unglued edges, YOU MUST RETURN IT TO YOUR PHARMACIST FOR REPLACEMENT.

    If you are unsure about how to check your device, your pharmacist can check your device for you.

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PLEASE INDICATE BELOW THE EPIPEN 0.3MG AND EPIPEN JR 0.15 MG INVENTORY OF THE LOTS WITH CARRIER TUBE ISSUE WHICH YOU ARE RETURNING							
DIN	**PRODUCT CODE**	**PRODUCT DESCRIPTION**	**SIZE**	**UPC**	**LOT #**	**EXPIRY DATE**	**UNITS RETURNED**
00509558	00121	Solution, 0.3 mg	Auto-Injector	625813 001213			
00578657	00111	Solution, 0.15 mg	Auto-Injector	625813 001114			

PLEASE COMPLETE THE FORM AND SEND TO INMAR BACK WITH YOUR EPIPEN RETURN.	
Customer Name:	
Wholesaler name:	
Wholesaler account number:	
Street Address:	
City:	
Province:	
Postal Code:	

Name of Authorised Person	Signature	Date

Please return all units of product identified above as well as a copy of this form by Purolator Collect (7983131) and waybill sender reference **PC092818** on the waybill to the following address:

Inmar MedTurn
50 Dynamic Drive,
Toronto, ON
M1V 2W2
Canada