Global EpiPen Recall Now Includes United States

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The United States has joined the list of countries covered by a voluntary recall of EpiPen auto-injectors for anaphylactic shock on account of a defective part that may result in the device failing to inject a potentially life-saving dose of epinephrine, the US Food and Drug Administration (FDA) announced today.

Mylan, the company that markets the device, announced earlier this month that it was recalling one lot of roughly 80,000 EpiPens in Australia, Europe, Japan, and New Zealand. It reported two instances of the device failing to deliver its dose. The patients in question, however, were treated successfully with backup, functioning EpiPens.

Pressing the EpiPen into a person's thigh — the prescribed area for administration — causes a needle to penetrate skin and inject epinephrine into muscle. The defective part may require a person to use increased force to activate the needle, or it may prevent the EpiPen from working at all, according to Mylan.

The company announced today that it was expanding the recall not only to the United States, but also other markets in North America and South America.

In the United States, the recall applies to 13 lots of both EpiPen and EpiPen Jr. auto-injectors distributed between December 17, 2015, and July 1, 2016. Patients can receive another EpiPen or an authorized generic version at their pharmacy, Mylan said. In the meantime, they should continue to carry and use their current EpiPen until they acquire a replacement.

Product/Dosage	NDC Number	Lot Number	Expiration Date
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM087	October 2017

Source: FDA

For further assistance, EpiPen users can contact Mylan at 800-796-9526 or email customer service at customer.service@mylan.com.

EpiPens are made by Meridian Medical Technologies, a subsidiary of Pfizer.

More information about today's announcement is available at the FDA website.

To report any problems with EpiPen and EpiPen Jr. auto-injectors, contact MedWatch, the FDA's safety information and adverse event reporting program, by telephone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm; with postage-paid FDA form 3500, available at http://www.fda.gov/MedWatch/getforms.htm; or by mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland 20852-9787.