Company Announcement

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Mylan Provides Update on Meridian Medical Technologies', a Pfizer Company, Expanded Voluntary Worldwide Recall of EpiPen® Auto-Injector

For Immediate Release

March 31, 2017

Contact

Consumers

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Announcement

View Product Photos

Mylan N.V. (NASDAQ, TASE: MYL) today announced that Meridian Medical Technologies, a Pfizer company and Mylan's manufacturing partner for EpiPen® Auto-Injector, has expanded a voluntary recall of select lots of EpiPen (epinephrine injection, USP) and EpiPen Jr® (epinephrine injection, USP) Auto-Injectors to now include additional lots distributed in the U.S. and other markets in consultation with the U.S. Food and Drug Administration (FDA).

This recall is being conducted as a result of the receipt of two previously disclosed reports outside of the U.S. 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). Both

reports are related to the single lot that was previously recalled. 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 expanded to include additional lots as a precautionary measure out of an abundance of caution.

The recalled product was manufactured by Meridian Medical Technologies, a Pfizer company, and distributed by Mylan Specialty between December 2015 and July 2016. The expanded voluntary recall is being initiated in the U.S. and also will extend to additional markets in Europe, Asia, North and South America.

The recall impacts the 0.3 mg and 0.15 mg strengths of EpiPen Auto-Injector. None of the recalled lots include the authorized generic for EpiPen Auto-Injector, which is also manufactured by Meridian Medical Technologies.

U.S. Impacted Lots:

Product/Dosage	NDC Number	Lot Number	Expiration Date
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen 2-pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM087	October 2017

Mylan is committed to replacing recalled devices at no cost and Mylan would like to reassure patients that there will be no additional replacement-related financial burden to them as a result of this recall. Patients, customers and distributors are being notified and should refer to **Mylan.com/EpiPenRecall (http://www.mylan.com/EpiPenRecall)** for updates on product return and replacement instructions. We are asking patients to keep their existing product until their replacement product can be secured.

Patients may receive either EpiPen Auto-Injector or the authorized generic for EpiPen Auto-Injector at the pharmacy as a replacement based on availability. The authorized generic has the exact same drug formulation, has the exact same operating instructions and is therapeutically equivalent to EpiPen Auto Injector, and may be substituted for EpiPen Auto Injector.

It is important that patients continue to carry their current EpiPen Auto-Injector until they receive a replacement device.

To return your product please contact Stericycle at 877-650-3494. If you have any additional questions regarding this recall, please contact Mylan Customer Relations at 800-796-9526 or **customer.service@mylan.com (mailto:customer.service@mylan.com)**.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of FDA.

Epinephrine is the first-line treatment for a life-threatening allergic reaction (anaphylaxis) and access to this product is critical in the event of an emergency. Delays in epinephrine administration have been associated with negative health consequences.

More information about the risks and benefits of EpiPen® Auto-Injector can be found at EpiPen.com.

Please see the full **Prescribing Information (https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7560c201-9246-487c-a13b-6295db04274a&type=display)** and **Patient Information (https://www.epipen.com/en/prescribing-information#Patient)**.

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