Mylan – Recall of EpiPen® and EpiPen Jr® Auto-Injectors

- On March 31, 2017, Mylan announced that Meridian Medical Technologies, a Pfizer company and Mylan's manufacturing partner for EpiPen (epinephrine) Auto-Injector, has expanded a voluntary recall of select lots of EpiPen and EpiPen Jr Auto-Injectors to now include additional lots distributed in the U.S. and other markets in consultation with the 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.

    — Both reports are related to a single lot that was previously recalled outside of the U.S.

- The recalled product was distributed from December 2015 through July 2016. None of the recalled lots include the authorized generic for EpiPen Auto-Injector, which is also manufactured by Meridian Medical Technologies.

Product Description	NDC #	Lot # (Expiration date)
EpiPen Jr 2-Pak Auto-Injectors, 0.15 mg	49502-501-02	5GN767 (4/2017), 5GN773 (4/2017), 6GN215 (9/2017)
EpiPen 2-Pak Auto-Injectors, 0.3 mg	49502-500-02	5GM631 (4/2017), 5GM640 (5/2017), 6GM082 (9/2017), 6GM072 (9/2017), 6GM081 (9/2017), 6GM088 (10/2017), 6GM199 (10/2017), 6GM091 (10/2017), 6GM198 (10/2017), 6GM087 (10/2017)

- EpiPen and EpiPen Jr are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects and biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

    — EpiPen and EpiPen Jr are intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

- 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.

- 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.

- Mylan is committed to replacing recalled devices at no cost and reassures patients that there will be no additional replacement-related financial burden to them as a result of this recall.

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

- 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

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drug formulation, operating instructions, is therapeutically equivalent to EpiPen Auto-Injector, and may be substituted for EpiPen Auto- Injector.

- Patients, customers and distributors are being notified and should refer to **www.Mylan.com/EpiPenRecall** for updates on product return and replacement instructions. To return recalled product, contact Stericycle at **1-877-650-3494**.

- For any questions regarding this recall, contact Mylan Customer Relations at **1-800-796-9526**.

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