EpiPen® (epinephrine) – Safety communication

- On November 2, 2018, the FDA announced that the labels attached to some EpiPen (epinephrine) 0.3 mg and EpiPen Jr (epinephrine) 0.15 mg auto-injectors, and the authorized generic versions, may block access to the auto-injector and prevent the ability to easily access the product.

- In a letter to healthcare professionals from Pfizer, the manufacturer of the Mylan EpiPen, the label sticker on the auto-injector unit may have been improperly applied, causing resistance when removing it from the carrier tube. The carrier tube is the immediate package in which the auto-injector is contained. In some cases, the patient or caregiver may not be able to quickly remove the epinephrine auto-injector from the carrier tube.

    — The probability of an auto-injector having a label that is not fully adhered is very low (approximately one auto-injector out of every 14,286 or 0.007%).
    — Although these are rare instances, delay in administration of EpiPen, EpiPen Jr, and the authorized generic versions of these strengths, has a possibility of being associated with progression to a more severe allergic reaction.
    — The issue is with the device label, and not with the device itself or the drug it delivers, epinephrine.

- Prior to dispensing EpiPen, EpiPen Jr and the authorized generic versions of these strengths to a patient, healthcare providers should ensure that the product can be easily removed from the carrier tube. If an auto-injector does not readily slide out of the carrier tube or the label is not fully adhered to the auto-injector, the auto-injector should not be dispensed.

    — Once the product is about to be dispensed, patients should be counseled to confirm that their auto-injector can be easily removed from the carrier tube prior to actual usage of the drug.
    — Patients need to be instructed that the auto-injector can still be used when the drug is returned to the carrier tube after inspection.

- The FDA is not aware of any adverse event reports associated with improperly applied EpiPen or EpiPen Jr auto-injectors, or their authorized generics label.

- Additional precautionary handling instructions can be found in the Pfizer letter to healthcare professionals.

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