Epinephrine auto-injector – Safety communication

- On June 1, 2020, the FDA alerted patients, caregivers and health care professionals to immediately inspect certain lots of Amneal and Impax epinephrine 0.3 mg auto-injectors to ensure the yellow "stop collar" in the device is present.

- If the auto-injector is missing the yellow "stop collar" component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient. It is vital for lifesaving products to work as designed in an emergency situation.

- In letters to health care professionals and consumers, Impax, a subsidiary of Amneal Pharmaceuticals, the manufacturer of the epinephrine auto-injector, detailed how certain lots of these devices might not contain the yellow "stop collar" component.

    — Refer to the healthcare care professional letter for the list of impacted lots.

- Patients, pharmacists and health care professionals who have received Amneal or Impax's epinephrine auto-injector after December 20, 2018, should immediately visually inspect the auto-injector to confirm the presence of the yellow "stop collar" by:

    — Removing the auto-injector from the carrying case.
    — Placing the auto-injector on a flat surface.
    — Locating the edge of the label that states, "Peel here for further instructions." Lift the label edge until you see the clear part of the auto-injector.
    — Looking for the yellow "stop collar" inside the clear part of the auto-injector. If the yellow "stop collar" is not visible inside the clear part of the auto-injector, gently rotate the blue sheath remover, without pulling or removing the blue sheath remover, to observe if the yellow "stop collar" comes into view inside the clear part of the auto-injector.
    — If yellow "stop collar" is present, then the product is safe to use, and no further action is necessary. Re-wrap the label to its original position and place the auto-injector into the carrying case.

- Patients and health care professionals should contact the Amneal Drug Safety Department at **1-877-835-5472** to assist in determining if the yellow "stop collar" is missing and to make arrangements to return defective devices and obtain a replacement at no additional cost. Patients should contact their pharmacy regarding a replacement epinephrine auto-injector before returning the defective device to Amneal.

- The FDA recommends that patients inspect their auto-injector devices as soon as possible and immediately contact the Amneal Drug Safety Department if they have questions about inspecting their auto-injector device, or if they're unsure if the yellow "stop collar" is missing.

- Pharmacists should inspect the products before dispensing them to patients to ensure the yellow "stop collar" is present. If the yellow "stop collar" is missing, pharmacists should not dispense the product and should contact Amneal.

- The yellow "stop collar" is one of several components that work together to assure proper dosing of the auto-injector. While some patients require a second dose of epinephrine, an epinephrine overdose has the potential to cause severe patient harm or death.

- As stated on the product label, consumers should always seek emergency medical help right away after using their epinephrine auto-injector.

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- The FDA reminds patients and health care professionals that epinephrine auto-injectors are available through additional manufacturers.

- The FDA is notifying patients and caregivers that epinephrine auto-injectors are not being recalled. The FDA urges patients and caregivers to use the epinephrine auto-injector they have on hand and be aware of the potential issues outlined in the statement above.

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