NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2015-06 **OCTOBER 30, 2015**

ITEM: **Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery**

SPECIFIC INCIDENT(S):

Auvi-Q ® (epinephrine injection, USP) is an auto-injector of epinephrine to be used for life-threatening allergic reactions. Sanofi US is voluntarily recalling all Auvi-Q ® (epinephrine injection, USP) because the products have been found to potentially have inaccurate dosage delivery.

- Sanofi received 26 reports of suspected (unconfirmed) device malfunctions as of October 26, 2015.
  - Patients have described symptoms of underlying hypersensitivity reaction.
  - No fatal outcomes occurred.
- Inaccurate dosage delivery of epinephrine may result in patients receiving a subtherapeutic dose to manage anaphylaxis symptoms, which can be life-threatening and lead to death.

GENERAL INFORMATION:

- This recall involves all Auvi-Q® (epinephrine injection, USP) currently on the market and includes both the 0.15 mg and 0.3 mg strengths for hospitals, retailers and consumers.
- Affected product includes lot numbers 2299596 through 3037230, which expire March 2016 through December 2016.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10151** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of Auvi-Q® (epinephrine injection, USP) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, allergy and immunology specialists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board

(IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 11/13/2015):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to use the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
      - In the event of a life-threatening allergic reaction (anaphylaxis), patients should only use their of Auvi-Q® (epinephrine injection, USP) device if another epinephrine auto-injector is not available, and then call 911 or local medical emergency services.
      - Patients should contact their provider if they have experienced any problems that may be related to taking or using of Auvi-Q® (epinephrine injection, USP).
  - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S):

1. FDA Safety Alerts for Human Medical Products: Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm470010.htm . (Accessed 10/29/2015)

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

2. FDA Recall - Firm Press Release: Sanofi US Issues Voluntary Nationwide Recall of Auvi-Q® Due to Potential Inaccurate Dosage Delivery. http://www.fda.gov/Safety/Recalls/ucm469980.htm . (Accessed 10/29/2015).

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION