NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2016-02 **APRIL 1, 2016**

ITEM: **Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution: Recall - Glass Particulate Matter**

SPECIFIC INCIDENT(S): Sanofi Genzyme announced a voluntary recall of one lot of Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution due to two reports of foreign matter identified as small glass fragments confirmed by investigation from each of the two returned product vials.

GENERAL INFORMATION:

- The administration of a glass particulate intravenously may result in foreign body reactions, local injection site reactions, allergic and hypersensitivity reactions, as well as blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.
- Affected product includes:

PRODUCT DESCRIPTION	LOT #	NDC	COUNTRY	EXPIRATION DATE
Carton/ Vial: Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution	E4029Y02	58468-1849-04	U.S.	SEP 2016
Carton/ Vial: Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution	E4029Y03	58468-0030-2	Brazil	DEC 2017
Carton/ Vial: Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution	E4029Y04	58468-0030-2	Israel	DEC 2017
Carton/ Vial: Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution	E4029Y06	58468-0030-2	Taiwan	DEC 2017
Carton/ Vial: Thyrogen® (thyrotropin alfa for injection) 0.9mg/mL after reconstitution	E4029Y07	58468-0030-2	Malaysia	DEC 2017

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10416** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with Thyrogen® (thyrotropin alfa for injection) 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, endocrinology staff, oncology staff, radiology, nuclear medicine, 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 4/15/2016):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Sites may not have lot number information available locally, so in the case that the lot number data is not available, sites will need to call all patients that received the product and ask them to check the lot numbers.
  - 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

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begin using the new product and return the recalled supply as instructed.

- 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): FDA Enforcement Report – Week of March 9, 2016. http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=select&recall_number=D-0729-2016&w=03092016&lang=eng .(Accessed 3/29/2016).

ATTACHMENT(S): None.

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