DEPARTMENT OF VETERANS AFFAIRS VETERAN HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) & MEDICAL ADVISORY PANEL (MAP)
VA CENTER FOR MEDICATION SAFETY (VAMedSAFE)

NATIONAL PBM COMMUNICATION · September 28, 2010

Voluntary Nationwide Recall of Certain Lots of Epoetin alfa (EPOGEN® and PROCRIT®)

- Amgen and Centocor Ortho Biotech Products, L.P., are announcing that they are voluntarily recalling specific lots of Epoetin alfa (EPOGEN® and PROCRIT®) that may contain extremely thin glass flakes (lamellae) formed from the interaction of the product with glass vials over the shelf life. These glass particles are barely visible in most cases.
- Vials containing glass particles may not maintain their sterile condition and should not be used for subcutaneous or intravenous injection if possible.
- Manufacturers report a low potential for reaction in patients who may have received the affected product.
- Possible serious adverse events associated with intravenous injection of sterile products that contain particulate matter include embolic, thrombotic and other vascular events (e.g., phlebitis).
- Possible serious adverse events associated with subcutaneous injection of sterile products that contain particulate matter include foreign body granuloma, local injection site reactions, and increased immunogenicity.
- To date, the presence of glass lamellae have not resulted in any reported complaints or adverse events.
- Epoetin alfa (EPOGEN® and PROCRIT®) is used in the management of patients with anemia.

- The following EPOGEN® (Epoetin alfa) products listed in the *Urgent: Drug Product Recall* in this link carry the affected lot numbers:
  - http://www.epogen.com/professional/pdf/epogen-consignee-notification-letter.pdf .
- The following PROCRIT® (Epoetin alfa) products listed in the *Urgent: Drug Product Recall* in this link carry the affected lot numbers:
  - http://www.procrit.com/sites/default/files/pdf/Supplier_Procrit_Recall_Letter.pdf .
- No other lots of this product are affected by this recall.

- Return all remaining product at the facility/CMOP level with the affected lot numbers as instructed in the product recall documents. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s) for home administration.
- If an affected lot was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - A sample letter can be found at:

http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc.

    - This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of medication.
    - How to return the medication being recalled to the pharmacy.
    - To continue taking the medication with the affected lot number until they receive a new supply. When correct medication is received, patient should begin taking the new medication and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this medication to the VA ADERS program.
- Refer to http://www.epogen.com/professional/pdf/epogen-consignee-notification-letter.pdf and http://www.procrit.com/sites/default/files/pdf/Supplier_Procrit_Recall_Letter.pdf for further details regarding this urgent drug recall and instructions for return of affected product.

ACTIONS:

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, hematology and oncology providers, kidney specialists, infectious disease specialists, gastroenterology providers, and Erythropoietin-Stimulating Agent (ESA) clinic 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. Report completion of actions to the Facility Director.*
- ***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).*
- ***VISN Directors:*** *Within 10 business days of receipt (due 10/13/2010), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*