

## NATIONAL PBM COMMUNICATION • October 5, 2012

### Compounded Epidural Steroid Injections and Meningitis Outbreak

- An outbreak of fungal meningitis associated with epidural steroid injections prepared and distributed by **New England Compounding Center, Inc (NECC)**, in Framingham, Massachusetts has resulted in 35 cases reported within 6 states, out of which 5 deaths have ensued.
- All infected patients received **preservative free methylprednisolone acetate 80mg/ml injection** from three lots voluntarily recalled by NECC on September 25, 2012, with lot numbers listed below:
  - Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, Beyond Use Date (BUD) 11/17/2012
  - Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
  - Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013
- Twenty-three states received one of the three recalled lots recalled by NECC: California, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, North Carolina, New Hampshire, New Jersey, Nevada, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, Texas, and West Virginia.
- Symptoms in infected patients occurred within 1-4 weeks post injection, and included fever, new or worsening headache, nausea, or signs consistent with stroke. Cerebrospinal fluid (CSF) showed findings consistent with meningitis. The form of fungal meningitis in these patients does not transmit from person to person.
- The Food and Drug Administration (FDA) used microscopic examination to detect fungal contamination (yet to be speciated) in a sealed vial of the finished dosage form of methylprednisolone acetate. FDA also observed foreign material in other vials produced by the company, with additional testing underway.
- NECC has since voluntarily suspended operations, surrendered their license, and expanded its recall to include all methylprednisolone acetate prepared by their specialty pharmacy as well as all of their other drug products designated for intrathecal administration. FDA will provide a listing of affected products when available.
- FDA continues to work with CDC and officials from Massachusetts and other states to investigate the source of contamination, scope of exposure, and impact on patient outcomes.

#### **PRODUCT SEQUESTERING ACTIONS**

- All healthcare practitioners must cease use and immediately remove from their pharmacy inventory ANY product produced by the NECC [not just methylprednisolone acetate (PF)].

#### **PATIENT NOTIFICATION ACTIONS**

- Clinicians must contact all patients who received methylprednisolone acetate (PF) injections from any of the three recalled lots to determine if they are having any symptoms.
  - Patients may be experiencing mild symptoms not typical of meningitis, such as new or worsening headache without fever or neck stiffness. If patients are having new or worsening symptoms, even mild symptoms, they should be evaluated immediately.
  - Patients who received other types of injections with methylprednisolone acetate from the three affected lots should also be contacted to assess for signs of infection, such as swelling, increasing pain, redness, and/or warmth at the injection site. If such symptoms do exist, patients should seek evaluation.
- If an affected lot(s) was administered to a patient(s), then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) by any appropriate method.
    - A sample letter can be found at:

[http://vawww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/OC%20Recall\\_Patient%20Letter%20Template.doc](http://vawww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/OC%20Recall_Patient%20Letter%20Template.doc)

This template can be altered according to site-specific needs.

- Provide patient(s) who received the recalled product with instructions on reporting to their respective VA medical center for further evaluation of signs/symptoms of meningitis as well as injection site reactions.
- Providers should continue to report any adverse reactions with the use of methylprednisolone acetate 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).

#### REFERENCES

CDC and FDA Joint Telebriefing on Investigation of Meningitis Outbreak. <http://www.cdc.gov/media/index.html>. (Accessed 10/04/12).  
Health Alert Network. CDC Health Advisory. Meningitis and Stroke Associated with Potentially Contaminated Product. <http://emergency.cdc.gov/HAN/han00327.asp>. (Accessed 10/05/12).

#### **NOTIFICATION ACTIONS:**

- **Facility Director (or physician designee):** Report completion of actions to the VISN Director.
- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, surgery, anesthesiology staff, pain specialists, neurology, 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. 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 issue (due 10/22/2012), communicate to the PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: [https://vawww.cmopnational.va.gov/cmop/PBM/visn\\_drug\\_recalls\\_alerts/default.aspx](https://vawww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx).