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 · May 12, 2011

Recall of Coumadin® (warfarin sodium) Crystalline 5mg tablets Due to High Potency

- Bristol-Myers Squibb is voluntarily recalling of one lot of Coumadin® (warfarin sodium) Crystalline 5mg tablets due to:
  - Higher potency found in a single tablet tested by the company; and
  - Increased risk for bleeding with greater active ingredient.
- To date, FDA has not received any reports of adverse events associated with Coumadin® (warfarin sodium) Crystalline 5mg tablets.

SEQUESTERING ACTIONS

- Following the action due dates in Product Recall Office Log # 1217 (available at http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining product at the CMOP/facility level with the affected lot numbers per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- The lot number affected in the U.S. is 9H49374A (1,000-count bottles) with an expiry date of September 30, 2012.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product was dispensed to any patient(s) for home administration using a 12-month time frame. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- 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) in possession of the recalled product with instructions on the following:
    - How to obtain a new supply of product.
    - How to return the product being recalled to the pharmacy.
    - Not to interrupt therapy. When the correct product is received, patient should begin using the new product and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this product to the VA ADERS program.

REFERENCES:

FDA Firm Press Release. http://www.fda.gov/Safety/Recalls/ucm253523.htm . (Accessed May 2, 2011).

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, cardiology, and anticoagulation 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 issue (due 5/26/2011), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*