

NATIONAL PBM COMMUNICATION · June 2, 2011

ADDENDUM: Expanded Recall of Coumadin® (warfarin sodium) Crystalline Tablets Due to High Potency

- On May 12, 2011, PBM issued a NATIONAL PBM COMMUNICATION addressing Bristol-Myers Squibb's voluntary recall of one lot of Coumadin® (warfarin sodium) Crystalline 5mg tablets for the following reasons:
 - Higher potency found in a single tablet tested by the company; and
 - Increased risk for bleeding with greater active ingredient.
- The recall has recently been expanded to include additional strengths of warfarin tablets and respective lot numbers due to the same active ingredient lot being used in the products' manufacture.

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 additional affected lot numbers appear below:

DESCRIPTION	LOT # & EXPIRATION DATE	NDC	UPC	ECONO#
COUMADIN TAB 10MG UD 100	9J53293D 10/2012	00056017475	30056017475	1883883
COUMADIN TAB 10MG 100	9J53293C 10/2012, 9J53293F 10/2012	00056017470	30056017470	1849876
COUMADIN TAB 10MG 100	9K50111A 10/2012	00056017470	30056017470	1849876
COUMADIN TAB 2.5MG 100	9J51681C 10/2012, 9J51684B 10/2012, 9K52102A 10/2012	00056017670	30056017670	1253285
COUMADIN TAB 2.5MG 1000	9J51678A 10/2012, 9J51686D 10/2012	00056017690	30056017690	1253293
COUMADIN TAB 4MG 100	9J54843A 10/2012	00056016870	30056016870	1453984
COUMADIN TAB 4MG 1000	9J54837B 10/2012, 9J54846A 10/2012	00056016890	30056016890	1454164
COUMADIN TAB 4MG UD 100	9J54837C 10/2012	00056016875	30056016875	1882505
COUMADIN TAB 7.5MG 100	9J49837A 09/2012, 9J49839B 09/2012	00056017370	30056017370	1253236
COUMADIN TAB 7.5MG UD 100	9J49837B 09/2012, 9J49839C 09/2012	00056017375	30056017375	1882836

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.

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 6/16/2011), 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.