NATIONAL PBM COMMUNICATION · November 9, 2012

Dabigatran (Pradaxa®) and Packaging Error - Recall Due to Possible Compromise in Product Quality

- Boehringer Ingelheim Pharmaceuticals Inc. is voluntarily initiating a drug recall of one lot of dabigatran (Pradaxa®) 75mg, at the **patient level**.
- A potential packaging defect in the affected lot may compromise bottle integrity, allowing moisture to get into the bottle which could impair the quality of the dabigatran (Pradaxa®) 75mg capsules.
- If patients do not receive a fully effective dose of dabigatran (Pradaxa®) 75mg, their risk of experiencing an ischemic stroke may increase.

SEQUESTERING ACTIONS

- Affected product and associated NDC number, lot number, and expiration date include:

Product	NDC No.	Lot No.	Exp. Date	Ship Dates to Wholesalers
Pradaxa®, (Dabigatran Etexilate), 75mg per Capsule, Bottle of 60	0597-0149-54	201900	JAN 2015	10/08/12– 10/15/12

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration from October 1, 2012 to present. CMOP has not purchased any of the affected NDC and LOT.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact patient(s) who may have received the affected product(s) 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.
        - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
        - Patients should continue to take the product as directed until they obtain replacement product to assure there is **no interruption of therapy.**
- Providers should continue to report any adverse reactions with the use of dabigatran (Pradaxa®) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported to the VA ADERS program (https://medora.va.gov/vaaders/medsafe_portal/index.asp), and from VA ADERS to the FDA (as appropriate) as VA ADERS enables completion of FDA MedWatch forms from the application with electronic submission directly to the FDA.

FEEDBACK 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, cardiology, 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 11/26/2012), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx .*