RE: Pradax® (dabigatran) Storage and Dispensing Considerations

A number of questions and concerns have been expressed regarding the storage and dispensing of Pradax® (dabigatran). Dabigatran tablets are hygroscopic and should thus not be removed from their original packaging. In Canada, dabigatran is available to pharmacies in bottles or blisters.

- **Stock Bottles:**
  If your pharmacy stocks bottles of Pradax®, the original bottle should be dispensed to the patient with instruction that the product must be used within 4 months following opening of the bottle (previous 1 month stability recently extended to 4 months based on new data).
  - Individual capsules should **NOT** be placed into dosettes or blister packs because they will lose potency.

- **Blisters:**
  The packaging of Pradax® capsules has been approved by Health Canada and guarantees that the product will be good for its pre-determined shelf life. Boehringer Ingelheim recommends that the Pradax® capsules are kept in the aluminium blister foil until just prior to taking them.
  - If your pharmacy prepares individualized dosettes/blister packages, ensure each Pradax® capsule remains in its original blister foil. This will require manually cutting around each Pradax® capsule and placing each capsule into the pharmacy-prepared dosette/blister pack in its original blister foil.

When choosing drug therapy, patient dexterity (ie: ability to open individually wrapped Pradax®), home care policies, and other considerations related to the unique restrictions around the dispensing and storage of Pradax® should be recognized, as an alternative medication may be more appropriate for a particular patient, given such restrictions.

Considering the potentially life-threatening consequences of sub-therapeutic levels of dabigatran, related to a decrease in potency, we recommend dispensing Pradax® as outlined above until more information is available.

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References: