Health Canada Endorsed Important Safety Information on Pradax® and Plavix®

November 3, 2011
Dear Health Care Professional:

Subject: **Risk of potential patient harm associated with brand name confusion involving Pradax® (dabigatran etexilate) and Plavix® (clopidogrel bisulfate).**

Boehringer Ingelheim (Canada) Ltd., and sanofi-aventis Canada Inc. (on behalf of Bristol-Myers Squibb Sanofi Canada partnership) in consultation with Health Canada, would like to alert you to the risk of medication errors associated with name confusion between the anticoagulant Pradax® (dabigatran etexilate) from Boehringer Ingelheim (Canada) Ltd. and the antiplatelet drug Plavix® (clopidogrel bisulfate) from sanofi-aventis Canada Inc.

Since January 2011, a total of 5 Canadian cases, associated with drug name confusion between Pradax® and Plavix®, have been received by Boehringer Ingelheim (Canada) Ltd. and Health Canada, including 1 case resulting in patient harm (non-serious bleeding after a medical procedure). An additional 2 reports of concern were received from health care professionals about the potential for confusion between the names of these two drugs.

- The Pradax® and Plavix® names, verbally and by script have been mistaken for one another. These mix-ups have been associated with similarities in orthographics, phonetics, strength, and use in patients with cardiovascular disorders.
- Receiving Pradax® instead of Plavix® or vice versa, may result in patient harm, including increased risk of bleeding, stroke, systemic embolism, venous thromboembolic events (VTE), atherothrombotic events or other unknown medical outcomes.
- The patient is also at risk of receiving incorrect concomitant medications or medical procedures when Pradax® or Plavix® is noted in patient history in error as a result of name confusion.
- To reduce the potential for name confusion errors, healthcare professionals are encouraged to include the generic name dabigatran when referring to Pradax®, or the name clopidogrel when referring to Plavix®. Spelling the name of the medication for verbal prescriptions or medication reconciliation (e.g. emergency room triage), is also suggested.

Pradax® (dabigatran), an oral anticoagulant (direct thrombin inhibitor), was first marketed in Canada in 2008, for the prevention of VTE in patients following hip or knee replacement surgery. In October 2010, Pradax® received a new indication for prevention of stroke and systemic embolism in patients with atrial fibrillation, in whom anticoagulation is appropriate. Pradax® is available in 75mg, 110mg and 150mg capsules.[1]

Plavix® (clopidogrel), an oral platelet aggregation inhibitor, was first marketed in Canada in 1998, for use as secondary prevention of atherothrombotic events (myocardial infarction or stroke) in patients with atherosclerosis. Plavix® is also indicated in combination with ASA for the prevention of atherothrombotic events in patients with acute coronary syndromes. In February 2011, Plavix® received a new indication, in combination with low-dose ASA, for the prevention of stroke in patients with atrial fibrillation, who are not suitable for treatment with an anticoagulant. Plavix® is available in 75mg and 300mg tablets.[2]

Boehringer Ingelheim Canada Ltd., and sanofi-aventis Canada Inc. (on behalf of Bristol-Myers Squibb Sanofi Canada partnership), in consultation with Health Canada, are working on measures to reduce the risk associated with medication errors related to name confusion issues between Pradax® and Plavix®.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of medication errors relating to name confusion between Pradax® and Plavix® should be reported to Boehringer Ingelheim (Canada) Ltd., sanofi-aventis Canada Inc, or Health Canada. Serious or unexpected adverse reactions in patients receiving Pradax®

should be reported to Boehringer Ingelheim (Canada) Ltd. or Health Canada. Any case of serious or unexpected adverse reactions in patients receiving Plavix® should be reported to sanofi-aventis Canada Inc. or to Health Canada. Medication incidents/errors can also be reported to the Institute for Safe Medication Practices (ISMP) Canada through the Canadian Medication Incident Reporting and Prevention System (http://www.ismp-canada.org/cmirps.htm).

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http://www.boehringer-ingelheim.ca/en/contact.html

sanofi-aventis Canada Inc.
2150 St-Elzear Blvd. West
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You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties.*

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522 Fax: 613-952-7738

For full prescribing and dosing information for Pradax® see Product Monograph.[1] For full prescribing and dosing information for Plavix® see Product Monograph.[2]

A copy of this letter can be found on the Boehringer Ingelheim (Canada) Ltd., website at: http://www.boehringer-ingelheim.ca/en/human_health/our_products.html and also at the sanofi-aventis Canada Inc. site: www.sanofi-aventis.ca

Sincerely,

original signed by

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Vice President, Medical and Regulatory Affairs
Boehringer Ingelheim (Canada) Ltd.

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References:

1. Pradax® Product Monograph, dated June 13, 2011
   http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

2. Plavix® Product Monograph, dated May 9, 2011
   http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp