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

November 8, 2011

Subject: **Risk of potential patient harm associated with name confusion involving the prescription drugs Pradax® and Plavix®.**

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 patients to the risk of medication errors associated with the mix-up of the names of two prescription drugs, Pradax® (dabigatran) and Plavix®(clopidogrel).

Pradax® is a blood thinner prescribed to patients who have a heart condition called atrial fibrillation (irregular heartbeat) to prevent strokes as well as to patients following hip or knee replacement surgery to prevent blood clots.[1] Plavix® helps keep platelets in the blood from sticking together and forming clots that could lead to heart attack or stroke. Plavix® combined with acetylsalicylic acid (ASA), can also be prescribed to patients with an irregular heartbeat that cannot take blood thinners.[2]

Since January 2011, there have been a total of 5 Canadian cases involving drug name mix-ups between Pradax® and Plavix®, including 1 case that resulted in patient harm (non-serious bleeding after a medical procedure). In addition, there have been 2 reports of concerns raised by health care professionals about potential for confusion between the names of these two drugs.

- Mix-ups between the drug names Pradax® and Plavix® have been associated with similarities in the names, when spoken or written, and in their use in patients with certain heart conditions or at risk of blood clots.
- Receiving Pradax® instead of Plavix® or vice versa, may result in patient harm, including increased risk of bleeding, stroke, heart attack or blood clots.
- Pradax® and Plavix® work in different ways and are used in different circumstances. Patients are encouraged to be aware of the names and uses of the medications they are taking and to keep a list of current medications with them. Should you have any questions regarding the prescription, contact your doctor or pharmacist.

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 of medication errors associated with name confusion between Pradax® and Plavix®.

As a patient or caregiver, there are several things that you can do to ensure you receive the correct medication and use it properly.

- Make sure that you can clearly read the name of the medication on any written prescription. If you cannot, you should ask your doctor to print the name on the prescription;
- Make sure you know why the doctor has prescribed the medication for you;
- Discuss with your pharmacist the reason why you are receiving the medication, the properties of the drug and asking any questions if not clear;
- Read the patient leaflet provided with the medication and ask any questions of your doctor or pharmacist;
- Know what your medications look like and raise any questions if there is a change in appearance;
- Keep an up-to-date list of all medications you are taking.
- Show this list to any doctor, pharmacist or dentist or if you are admitted to a hospital; or bring all the medications you are currently taking with you.

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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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

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

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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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