Health Canada Endorsed Important Safety Information on CHAMPIX (varenicline tartrate)

May 31, 2010

Dear Healthcare Professional,

Subject: Important safety information regarding CHAMPIX® (varenicline tartrate)

Pfizer Canada, in collaboration with Health Canada, would like to inform you of important changes to the Product Monograph for CHAMPIX®, including changes to the Consumer Information section.

These changes include:

- The addition of a BOXED WARNING highlighting important recommendations for healthcare professionals regarding information related to neuropsychiatric adverse events;
- A warning regarding rare reports of hypersensitivity reactions, such as angioedema and serious skin reactions, including Stevens-Johnson syndrome and erythema multiforme;
- The addition of an "Information for Patients" section under *WARNINGS and PRECAUTIONS* providing prescribers with advice regarding key information to be shared with their patients prior to and during treatment; and
- Two dosing options are now approved for CHAMPIX®. Following one week titration, the dose may be increased to a maximum of 1.0 mg twice daily or remain at 0.5 mg twice daily.

CHAMPIX® (varenicline tartrate) is indicated for smoking-cessation treatment in adults in conjunction with smoking-cessation counselling. When prescribing CHAMPIX®, healthcare professionals should discuss with patients its benefits and risks.

There have been continuing Canadian and International post-marketing reports of serious neuropsychiatric symptoms, such as depressed mood, agitation, aggression, hostility, changes in behaviour, suicide related events and worsening of pre-existing psychiatric disorder in patients treated with CHAMPIX®. **These events have occurred in patients with and without pre-existing psychiatric disorder.** Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Alcohol intake may also increase the risk of patients experiencing psychiatric adverse events during treatment with CHAMPIX®. Patients should stop treatment with CHAMPIX® and contact their healthcare provider immediately if they have, or if their families or caregivers observe, neuropsychiatric symptoms or behaviours that are not typical for the patient.

There have been post-marketing reports of somnolence, dizziness, loss of consciousness, seizures or difficulty concentrating, therefore, patients should be advised not to engage in potentially hazardous activities, such as driving a car or operating dangerous machinery until they know how they may be affected by CHAMPIX®.

There have also been post-marketing reports of patients experiencing hypersensitivity reactions, such as rare life-threatening angioedema events requiring urgent medical attention and rare severe cutaneous reactions, including Stevens-Johnson syndrome and erythema multiforme. Patients should immediately stop treatment with CHAMPIX®

and seek emergency medical care if they experience any signs or symptoms of severe skin/hypersensitivity reactions.

There are now two dosing options approved for CHAMPIX®. Following one week titration, the dose may be increased to a maximum of 1.0 mg twice daily or remain at 0.5 mg twice daily. The dose should be chosen, based on physician judgement of patient tolerance, perceived effectiveness of the treatment, and patient preference. The dosing regimen may be switched temporarily or permanently between these two options, if needed, subsequently.

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 serious or unexpected adverse reactions in patients receiving CHAMPIX® should be reported to Pfizer Canada or Health Canada at the following addresses:

Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
Telephone: 1-800-463-6001

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701D
Ottawa, Ontario, K1A 0K9
Telephone: 613-957-0337 or Fax: 613-957-0335
CanadaVigilance@hc-sc.gc.ca

To report an Adverse Reaction, consumers and health professionals may call toll free:
Telephone: 1-866-234-2345
Fax: 1-866-678-6789

Postage paid labels, the Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties.*

http://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

Sincerely,

original signed by

Bernard Prigent, MD, MBA
Vice-President and Medical Director
Pfizer Canada Inc.