

**PUBLIC COMMUNICATION**  
**Health Canada-Mandated Important Safety Information on**  
**PERMAX<sup>®</sup> (pergolide mesylate)**



August 16, 2007

**Subject: Manufacturer Sales of Permax<sup>®</sup> (pergolide mesylate) Will Stop in Canada as of August 30, 2007**

Eli Lilly Canada Inc., in co-operation with Health Canada, will stop sales of Permax (pergolide mesylate) in Canada as of August 30, 2007 due to the potential for cardiac valvulopathy, a condition involving inflammation or stiffening of the heart valves. Pharmacies may continue to sell Permax after that date to allow patients sufficient time to consult with their healthcare providers and to transition to an alternative medication.

Permax is a member of a class of drugs known as dopamine agonists and has been marketed in Canada since 1991 for the treatment of Parkinson's disease. The risk of heart valve problems was first described in association with Permax in 2002. Over the years, the prescribing information for Permax was modified accordingly to include the latest safety information, and these safety concerns were communicated to Canadian healthcare professionals and patients in 2003 and again in 2004.

Two studies published in the New England Journal of Medicine (NEJM) in January 2007 showed that patients with Parkinson's disease who were treated with Permax had an increased chance of serious heart valve damage when compared to patients who did not receive the drug.<sup>1,2</sup> In light of this recent information, Health Canada has determined that there is not enough evidence to support the continued safe use of Permax as currently recommended in the prescribing information.

- Patients should NOT stop taking Permax without first consulting their healthcare provider, since stopping Permax too quickly can lead to serious side effects.
- Patients currently using Permax should contact their healthcare provider as soon as possible to discuss alternative treatment options.
- Pharmacies may continue to sell Permax to ensure that patients have enough medication to last until they can see their healthcare providers and safely switch to another medication.

Eli Lilly Canada Inc. and Health Canada anticipate there will be sufficient supplies in pharmacies to allow enough time for patients to safely switch to another product. Should pharmacy supplies run out and/or patients cannot be safely transitioned to other available anti-Parkinson's medications, physicians may contact the Special Access Programme at Health Canada to request temporary access to the drug for individual patients. In most cases, alternative therapies are available to treat Parkinson's disease. Availability of Permax through the Special Access Programme may be an option for patients who have failed to respond to alternative therapies. Information on the Special Access Programme is available on the Health Canada website at:

[http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapfs\\_pasfd\\_2002\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapfs_pasfd_2002_e.html).

Eli Lilly Canada has sent a letter to Canadian healthcare professionals informing them of this new safety information and that sales will stop as of August 30, 2007. A copy of the healthcare professional letter and

this communication are available on the Health Canada website at:  
[http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html).

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected adverse reactions in patients receiving Permax® should be reported to Eli Lilly Canada or Health Canada, at the following addresses:

Customer Response Centre  
Eli Lilly Canada Inc.  
3650 Danforth Avenue  
Toronto, Ontario, M1N 2E8  
Tel.: 1-888-545-5972  
Fax: 1-888-898-2961

**Any suspected adverse reaction can also be reported to:**

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)  
Marketed Health Products Directorate

HEALTH CANADA

Address Locator: 0701C

OTTAWA, Ontario, K1A 0K9

Tel: (613) 957-0337 or Fax: (613) 957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:

Tel: 866 234-2345

Fax: 866 678-6789

[cadrmp@hc-sc.gc.ca](mailto:cadrmp@hc-sc.gc.ca)

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei\\_form\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html)

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei\\_guide-ldir\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html)

**For other inquiries related to this communication, please contact Health Canada at:**

Marketed Health Products Directorate (MHPD)

E-mail: [MHPD\\_DPSC@hc-sc.gc.ca](mailto:MHPD_DPSC@hc-sc.gc.ca)

Tel: (613) 954-6522

Fax: (613) 952-7738

The safety of patients remains a top priority for Eli Lilly Canada Inc. Should you have any questions about Permax, please contact the Eli Lilly Canada Customer Response Centre at 1-888-545-5972.

Sincerely,



Loren D. Grossman, MD, FRCPC, FACP  
Vice President, Research and Development  
Eli Lilly Canada Inc.

Permax® is a registered trademark of Eli Lilly and Company.

**References**

1. Schade R, Andersohn F, Suissa S, et al. Dopamine agonists and the risk of cardiac-valve regurgitation. *N Engl J Med* 2007;356:29-38.
2. Zanettini R, Antonini A, Gatto G, et al. Valvular heart disease and the use of dopamine agonists for Parkinson's disease. *N Engl J Med* 2007;356:39-46.