PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
[Pr]MACUGEN* (pegaptanib sodium injection)

2006 January 12

Subject: **Association of [Pr]MACUGEN* (pegaptanib sodium injection) with reports of allergic reactions**

Kirkland, Quebec – January, 2006 – Pfizer Canada Inc., following discussions with Health Canada, wishes to provide Canadians with important new safety information regarding rare reports of allergic reactions, ranging from mild to severe, in patients who have received MACUGEN (pegaptanib sodium injection).

MACUGEN is a drug, injected into the eye by ophthalmologists, for the treatment of a form of age-related macular degeneration (AMD). AMD leads to vision loss resulting from damage to the central part of the retina (called the macula), at the back of the eye.

There have been rare reports of hypersensitivity or allergic reactions ranging from mild to severe, following the procedure to inject MACUGEN into the eye. Such allergic reactions can be life threatening. There have been no Canadian reports of such allergic reactions.

Since the injection procedure includes various steps (e.g., anesthesia, antibiotics, possibly latex gloves), a direct relationship to MACUGEN or other factors has not been established in these cases.

Please note the following important information about MACUGEN:

- You should not receive MACUGEN if you are allergic to pegaptanib sodium or any of the other ingredients of MACUGEN or products used in the injection procedure.
- You should inform your ophthalmologist of any medical history of allergic type reactions prior to the injection procedure.

Pfizer Canada Inc. has sent a letter to Canadian ophthalmologists informing them of this new safety information. You may view this letter on Pfizer Canada's website (www.pfizer.ca) or on the website of Health Canada (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/index_e.html). Pfizer Canada is currently working with Health Canada to revise the Canadian prescribing information for MACUGEN. If patients have questions, they should discuss these with their ophthalmologist.

Managing marketed health product-related adverse reactions depends on the active participation of the healthcare professionals and consumers reporting them. Spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments.

Any occurrence of hypersensitivity, including severe allergic reactions or any other serious or unexpected adverse reactions in patients receiving MACUGEN should be reported to Pfizer Canada Inc. or Health Canada at the following addresses:

*TM Eyetech Pharmaceuticals Inc., Pfizer Canada Inc., licensee

Pfizer Canada Inc.
Drug Safety
P.O. Box 800
Pointe-Claire- Dorval, Quebec
H9R 4V2
Tel: 1 800 463-6001 (Medical Information)

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

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/guide/ar-ei_guide-ldir_e.html

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

For media inquiries, please contact Mr. Michael Amos, Pfizer Canada Inc., (514) 693-4587.

Sincerely,

Bernard Prigent, M.D.
Vice-President and Medical Director
Pfizer Canada Inc.

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