

**PUBLIC COMMUNICATION**  
**Health Canada Endorsed Important Safety Information on AVASTIN® (bevacizumab)**



December 16, 2008

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, has informed Canadian healthcare professionals of important new safety information concerning the unauthorized use of AVASTIN® (bevacizumab) when injected into the eye.

**Subject: Reports of cases of eye inflammation following the unauthorized use of AVASTIN in the eye**

AVASTIN is used together with other drugs to treat cancer of the large bowel and rectum which has spread to other parts of the body.

AVASTIN was specifically developed to treat cancer by injection into the veins. AVASTIN was not developed to be injected into the eye. The use of AVASTIN in the eye has not been reviewed or authorized by Health Canada.

Roche has been made aware of a number of cases of eye inflammation following the injection of AVASTIN into the eye. The majority of these cases were seen in patients who were injected AVASTIN Lot B3002B028 into the eye. The quality standards for Lot B3002B028 were reviewed and all tests were well within the limits established for the authorized use of AVASTIN. Other investigations are currently ongoing.

There was no unusual reporting of side effects for people who received this lot for the treatment of cancer in 2008.

The signs and symptoms of this type of reaction in the eye are:

- Eye pain or burning sensation
- Floaters
- Blurred vision
- Eye redness
- Increased eye pressure (found on examination by your doctor)

It is important to see your eye doctor if you have any of these symptoms after an eye injection with AVASTIN. Treatment is important and available for this condition.

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 occurrence of serious and/or unexpected adverse reactions in patients receiving AVASTIN should be reported to Hoffmann-La Roche Limited or Health Canada at the following addresses:

Hoffmann-La Roche Limited  
Drug Safety Department  
2455 Meadowpine Boulevard  
Mississauga, Ontario, L5N 6L7  
or call toll free at: 1-888-762-4388  
or Fax at: 905-542-5864  
or email to: [mississauga.drug\\_safety@roche.com](mailto:mississauga.drug_safety@roche.com)

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

Canada Vigilance Program  
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  
[CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@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*.

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

Marketed Health Products Directorate (MHPD)  
E-mail: [mhpd\\_dpssc@hc-sc.gc.ca](mailto:mhpd_dpssc@hc-sc.gc.ca)  
Tel: (613) 954-6522  
Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of AVASTIN, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time.

Sincerely,

*original signed by*



Lorenzo Biondi,  
Vice President, Medical and Regulatory Affairs  
Hoffmann-La Roche Limited