Public Communication -
Health Canada Endorsed Important Safety Information on
RITUXAN® (rituximab)

February 25, 2013

Subject: Association of Severe Skin Reactions with RITUXAN

Hoffmann-La Roche Limited, in consultation with Health Canada, has informed health care professionals of important safety information regarding RITUXAN (rituximab).

RITUXAN is a medication that is given by intravenous infusion to treat cancer of the lymph cells and bone marrow. RITUXAN may also be used to reduce the signs and symptoms of rheumatoid arthritis (RA) and to reduce inflammation associated with severe Granulomatosis with Polyangiitis (GPA), also known as Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

- Severe skin reactions such as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS) have been reported very rarely in patients who were given RITUXAN for the treatment of cancer or disorders of the immune system such as rheumatoid arthritis (RA). Some cases resulted in death.

- Signs and symptoms of severe skin reactions may include flu like symptoms; fever; itching of the skin; painful, red or purplish skin rash that spreads and blisters causing the top of the skin to shed; mouth sores; eye burning, itching and discharge. These may occur on the day of infusion, within a few days, a week, or up to four months following the infusion.

- If you develop any of the above or any other unusual signs or symptoms, please contact your doctor or healthcare professional immediately.

- If a severe skin reaction occurs, RITUXAN administration needs to be stopped. A healthcare professional will decide whether to re-administer RITUXAN.

The prescribing information already includes information on these skin reactions for patients who are taking RITUXAN for the treatment of cancer. Based on the new safety information for patients who are taking RITUXAN for the treatment of rheumatoid arthritis (RA), Roche will be working with Health Canada to update the prescribing information accordingly.

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Hoffmann-La Roche has sent a letter to healthcare professionals informing them of this important safety information. This information may be obtained on the Canadian website of Hoffmann-La Roche Limited or on the Health Canada Web site.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome or other serious or unexpected side effects in patients receiving RITUXAN should be reported to Hoffmann-La Roche Limited or Health Canada.

Hoffmann-La Roche Limited
Drug Safety Department
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or call toll free at: 1-888-762-4388
or Fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

You can report any suspected side effect associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
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Should you have any questions or require additional information regarding the use of RITUXAN, 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.

Lorenzo Biondi,
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