PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on CellCept® (mycophenolate mofetil)

June 3, 2009

Subject: Reports of Pure Red Cell Aplasia in Patients Treated with CellCept® (mycophenolate mofetil)

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, has informed Canadian healthcare professionals of important new safety information regarding reports of a type of anemia called pure red cell aplasia (PRCA) in patients treated with CellCept® (mycophenolate mofetil).

CellCept is authorized for the prevention of organ rejection in adults receiving kidney, heart or liver transplants, and in children and adolescents (2-18 years) receiving kidney transplants. CellCept should be used in combination with other anti-rejection drugs such as cyclosporine and corticosteroids.

- Cases of PRCA have been reported in patients treated with CellCept in combination with other anti-rejection drugs.
- In some cases, PRCA was found to be reversible when the dosage of CellCept was reduced or CellCept therapy was discontinued. There may be a risk to the transplanted organ if anti-rejection medications, such as CellCept, are reduced in dosage or discontinued.
- **Patients taking CellCept and any other prescribed anti-rejection medications should not discontinue or change their medication without discussion with their transplant physician.**

PRCA is a condition in which a patient develops severe anaemia due to failure of the bone marrow to produce red blood cells and is characterized by a severe and sudden anaemia accompanied by the feeling of tiredness or shortness of breath. You should consult your transplant physician immediately if you are feeling unusually tired or short of breath.

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 CellCept 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

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

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/ar-ei_form-eng.php
http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_fs-if/2009-ar-ei-guide-patient/index-eng.php

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
Tel: (613) 954-6522
Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of CellCept, 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.

original signed by

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Hoffmann-La Roche Limited