Therapeutic Products Directorate (TPD) and Biologic and Genetic Therapies Directorate (BGTD) posts safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although TPD and BGTD approve therapeutic products, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Hoffmann-La Roche Ltd.**
Contact the company for a copy of any references, attachments or enclosures.

May 16, 2001

Roche

Pharmaceuticals

IMPORTANT DRUG WARNING

Dear Health Professional,

Hoffmann-La Roche Ltd. would like to inform you of important updated serious adverse event information identified during post-market use of Rituxan® (rituximab). 'Rituxan' is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkin's lymphoma. To date, approximately 100 000 patients world-wide have been treated with 'Rituxan'.

There have been 20 post-marketing reports worldwide of severe mucocutaneous reactions associated with the use of 'Rituxan'. Eight of these resulted in fatal outcomes. These reactions are variably described as Stevens-Johnson Syndrome, toxic epidermal necrolysis, paraneoplastic pemphigus, lichenoid dermatitis or vesiculobullous dermatitis. The onset of the reaction in the reported cases has varied from days to several months following 'Rituxan' exposure. No definitive predisposing factors have been identified. Patients experiencing a severe mucocutaneous reaction should interrupt treatment with 'Rituxan' and seek prompt medical evaluation. Skin biopsy of these reactions may help to establish a diagnosis and guide subsequent treatment. The safety of readministration of 'Rituxan' in these patients has not been determined.

Severe bullous skin reactions (including toxic epidermal necrolysis and pemphigus) were previously described in the ADVERSE EVENTS, Post Marketing Experience section of the Product Monograph. However, as a result of a review of these cases, the Warnings section of the Product Monograph will be revised to include information regarding severe mucocutaneous skin reactions.

Hoffmann-La Roche Ltd. is committed to providing you with the most up-to-date and accurate information regarding its products. Should you have any questions regarding the use of 'Rituxan', please contact our Drug Information and Safety Department at 1-888-ROCHE88 or through our Fax-on-Demand® system at 1-888-ROCHEFX or via the internet at www.rochecanada.com.

You can further our understanding of adverse events by reporting all cases to Hoffmann-La Roche Ltd. at 1-888-ROCHE88 or to Health Canada by telephone: (613) 957-0337, by fax: (613) 957-0335 or by email: cadrmp@hc-sc.gc.ca.

Sincerely,

HOFFMANN-LA ROCHE LTD.

Lorenzo Biondi, M.Sc.Phm.
V.P. Drug Regulation, Information and Quality

Hoffmann-La Roche Limited 2455 Medowpine Boulevard Tel. (905) 542-5555
Mississauga, Ontario L5N 6L7 Fax (905) 542-7130

Any suspected adverse drug reactions can also be reported to:

Canadian Adverse Reaction Monitoring Program (CADRMP)
Bureau of Licensed Product Assessment
Therapeutic Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
cadrmp@hc-sc.gc.ca

The ADR Reporting Form can be found in *The Canadian Compendium of Pharmaceutical and Specialties*, or on the TPD website, along with the ADR Guidelines at:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/forms/adverse_e.pdf
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/adr/adr_guideline_e.pdf