CANADIAN ASSOCIATION OF GASTROENTEROLOGY
L'ASSOCIATION CANADIENNE DE GASTROENTÉROLOGIE

CAG/ACG National Office, 2902 South Sheridan Way, Oakville, Ontario L6J 7L6 CANADA
Telephone: 905.829.2504 *Fax*: 905.829.0242 *Toll Free*: 1.888.780.0007
E-mail: cagoffice@cag-acg.org *Website*: http://www.cag-acg.org

March 7, 2003

The Honourable Jane S. Purves
Minister of Health
Joseph Howe Building
Fourth Floor
1690 Hollis Street
Halifax, NS B3J 2R8

< <Sent by facsimile to: 902-424-0559, original by mail> >

Dear Ms. Purves,

I write in my capacity as President of the Canadian Association of Gastroenterology (CAG) to express our concern with regard to the proposed changes to proton pump inhibitor coverage in Nova Scotia.

The CAG is the national organization of Gastroenterologists in Canada focused on educational and research initiatives for Canadian physicians and researchers in the field. In addition, the CAG orchestrates the regional Gastroenterology associations as a formal body of the organization (Regional Representation Committee) and this includes the Atlantic Association of Gastroenterology.

We are not aware of any direct communication from your Department to the regional or national Gastroenterology Associations, but we understand that you have two main issues under consideration.

The first concern is that of substitution with rabeprazole in patients whose symptoms/disease are currently safely and effectively controlled on other proton pump inhibitors. This is not desirable because disruption of treatment in a patient who is doing well cannot be justified for the following reasons:

1. Government is intervening in the therapeutic relationship between patient and physician. A course of therapy has been decided in confidential discussion between the two parties. We strongly feel that a Government agency has no ethical right to interfere in treatment without the consent of **both physician and patient.**
2. These patients may become symptomatic upon switch of medication. If they do, it is likely, given the waiting time for GI consultation in Nova Scotia, that their symptoms will not receive prompt attention.
3. Even if they do not become symptomatic (which is the case in a large proportion of patients with reflux disease) they may be exposed to the risk of complications of their underlying illness. Since head to head efficacy studies have not been performed for the PPI's they cannot be assumed to have equivalent effects.

…Page 2

4. Many elderly patients are likely taking NSAID's. There is evidence that omeprazole and lansoprazole are effective in treating NSAID associated ulcers and preventing recurrence. There is no such evidence for rabeprazole. We are concerned that substitution with rabeprazole may result in gastrointestinal complications such as hemorrhage, particularly as there is likely to be confusion surrounding the dose being 10 mg o.d., 10 mg b.i.d. or 20 mg o.d (20 mg o.d. is the standard treatment dose in these patients). Should such a complication occur we would like to make it clear that the medico-legal responsibility will rest entirely with the Nova Scotia Department of Health and not with the Gastroenterology Associations.

The second issue is that of defining rabeprazole as the first-line proton pump inhibitor in Nova Scotia. We feel that this is premature because;

1. There are no studies showing comparable efficacy between rabeprazole and the other PPI's.
2. Rabeprazole has not been approved for eradication of *Helicobacter pylori* infection or for prevention of NSAID induced gastroduodenal ulceration. To position one drug as the only option, when there are no research studies to support the indication, is contrary to the practice of evidence-based medicine, a disincentive to industry to conduct sound clinical research, and subsequently provide essential investment within Canada.

We hope that these indications will be factored into your decision.

Should the Nova Scotia Department of Health proceed with this policy change we hope that you will recommend the single 20 mg tablet of rabeprazole as opposed to insisting that this elderly group of patients take two 10 mg tablets. At first glance this may not appear to be a major issue however the data showing that decreased compliance is related to the increased number of medications is convincing. In the elderly population, many of who are already on multiple drugs we feel that it is important to not add to this burden. Moreover, the correct dose of this drug is 20 mg o.d., half to one hour before the first meal of the day.

Finally, if major changes to the treatments for patients with GI diseases are contemplated in the future, we hope that the CAG, and / or the regional Gastroenterology Association, will have the opportunity to comment in advance and assist you with your decision.

I hope you will appreciate the concerns of the gastroenterology community in Canada with regard to this important issue. However, this is only one of many such situations such as the difficulty experienced with appropriate reimbursement for remicade in patients with Crohn's disease, the lack of appropriate reimbursement of the coxibs, while patients continue to die from the complications of non-selective NSAIDs and the lack of reimbursement of tegaserod for patients with IBS with constipation.

We look forward to establishing a meaningful dialogue with you in the future to work together to resolve this worsening state of affairs.

Sincerely

Philip M. Sherman, MD, FRCP(C)
President, CAG
Professor, Departments of Pediatrics & Microbiology
Hospital for Sick Children, University of Toronto
Canada Research Chair in Gastrointestinal Disease

John L. Wallace, PhD
Past President, CAG
Professor, Dept. of Pharmacology & Therapeutics
University of Calgary

c: The Honourable John F. Hamm, Premier, Government of Nova Scotia
Dr. Robert Miller, President, The Medical Society of Nova Scotia
Ms. Eleanor Hubbard, Director, Insured Programs, Nova Scotia Pharmacare Department
Ms. Emily Somers, Manager Drug Programs, Nova Scotia Department of Health