

February 24, 2005

Sent Via Email

Ms. Susan Bincoletto
Acting Director General
Marketplace Framework Policy Branch
Industry Canada
10th Floor, East Tower
235 Queen Street
Ottawa ON
K1A 0H5

Dr. Robert Peterson
Director General, Therapeutic Products Directorate
Health Products and Food Branch, Department of Health
1600 Scott Street
Holland Cross, Tower B
6th Floor, Address Locator No. 3106B
Ottawa, Ontario
K1A 0K9

**Re: Regulations Amending the *Patented Medicines (Notice of Compliance) Regulations*
Canada Gazette, Part I
Notice Dated December 11, 2004**

**Re: Regulations Amending the *Food and Drug Regulations* (1390 – Data Protection)
Canada Gazette, Part I
Notice Dated December 11, 2004**

We are writing in response to the government's proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* (the "NOC Regulations" or the "Regulations"), and the *Food and Drug Regulations* as published in the *Canada Gazette*, Volume 138, Number 50 on December 11, 2004.

We are a coalition of Canadian consumers who are concerned about the rising cost of prescription drug products in Canada. The following groups are members of our coalition: Canadian Pensioners Concerned Incorporated, National Union of Public and General Employees, Congress of Union Retirees of Canada, Canadian Health Coalition, Consumers' Association of Canada, Alliance of Seniors, National Pensioners and Senior Citizens Federation Incorporated, and Ontario Society (Coalition) of Senior Citizens Organizations.

We are submitting comments on these proposed changes to the Regulations affecting drug approvals in Canada because of the substantial and negative effect that these regulations have on the timely approval of affordable medicines.

Summary of Our Position

The government's proposed amendments to the Regulations do nothing to improve Canadians' timely access to affordable medicines.

The NOC Regulations are a critical impediment to access to affordable medicines in Canada. The NOC Regulations create a strong incentive for brand name pharmaceutical companies to manipulate the timing and release of patents, and the listing of patents on the Patent Register in such a way as to prevent competition.

Our comments on the government's proposed amendments to the Regulations can be summarized as follows:

- (i) The NOC Regulations should be repealed;
- (ii) While it appears that the government has tried to close some of the loopholes existing in the current Regulations, in our view, the government's proposed amendments still provide opportunity for unnecessary and unjustified delays;
- (iii) If the government refuses to eliminate the NOC Regulations in their entirety, the government should adopt an easy to administer, clear-cut rule, namely that only the patents that are on the Patent Register when a generic company makes its submission to Health Canada should be able to delay approval of a generic product;
- (iv) There should be compensation for Canadian consumers, third-party payers, taxpayers and governments (collectively, "Drug Purchasers") who have paid too much for drugs because of brand name companies' engineering of unnecessary and unjustified delays in the approval of safe and effective, lower cost pharmaceutical products; and
- (v) The proposed amendments to the *Food and Drug Regulations* regarding data protection are unnecessary and contrary to the overall goal of the government's proposed reforms.

Background

We do not believe it is generally known in Canada that there are numerous examples of delay in the approval of lower cost, safe and effective drugs which literally cost taxpayers and consumers hundreds of millions of dollars per year. This is money that would otherwise be available for other healthcare related spending.

Recently, federal and provincial government leaders met to talk about how to ensure Canadians receive high quality medical care. How can this government claim to be working toward ensuring that all Canadians have access to our healthcare system, yet at the same time keep in place an antiquated regulatory regime that artificially increases the costs of pharmaceuticals?

The NOC Regulations Should be Repealed

The NOC Regulations should be eliminated in their entirety. In our view, the Regulations are not needed at all.

Patent laws exist to protect patentees. Only in the case of pharmaceuticals are patentees entitled to delay a proposed competitor from entering the market. The Regulations provide brand name companies with an opportunity to prevent generic competition by merely listing patents on the Patent Register and automatically benefiting from successive, staggered, 24-month delays. No other category of patent holders has been given such extraordinary rights, and the result of this extraordinary privilege to brand name companies is contrary to the public's interest in having access to affordable medicines.

We are aware that in the majority of cases, the generic company that has been delayed ultimately wins the court battle, and may be entitled to damages. However, brand name companies who benefit from improper delays never have to fully relinquish all of the profits made during the period of improper delay. Specifically, Drug Purchasers are never reimbursed the additional money paid for the higher cost product during the period of unnecessary and unjustified delay.

Thus, there is a built-in incentive for brand name companies to delay generic approvals, with disastrous consequences on the timely marketing of affordable generic drugs.

For several years now, we have been writing different levels of government to express our concern with the NOC Regulations. For example, in May 2003, we submitted an application for inquiry under section 9 of the *Competition Act* urging the Commissioner of Competition to commence an inquiry into patent evergreening and the effect of evergreening on Drug Purchasers, as well as provide comments on the interpretation of the NOC Regulations and their impact on competition in pharmaceutical products. The Commissioner of Competition had this to say about the operation of the NOC Regulations:

...a number of court decisions over the last several years regarding what constitutes a relevant patent and the time period during which such a patent can be added [to the Patent Register] have somewhat altered the balance contained in the NOC Regulations between the competing interests of the brand name pharmaceutical patent holders and generic drug companies. Furthermore, I note that there is no ready mechanism in

the NOC Regulations for compensating consumers affected by delays in the introduction of generic drugs, thereby creating a possible incentive for brand name pharmaceutical companies to strategically use the NOC Regulations to improperly delay generic drug entry.

Therefore, from a competition policy perspective in particular, the Government may wish to review the current regulatory process established by the NOC Regulations to ensure that an appropriate balance be maintained between protecting intellectual property rights and encouraging a competitive supply of pharmaceutical products for consumers. [emphasis added]

The Romanow Commission, which undertook a two-year comprehensive review of Canada's healthcare system, expressed a similar concern about the practice of brand name "evergreening" of patents:

...manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage. This delays the ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada's patent law ... Clearly, if this is the case, the practice is not in the public interest.¹ [emphasis added]

In our complaint to the Competition Bureau, we discussed two cases of evergreening: omeprazole and paroxetine. The accumulated loss to Drug Purchasers from expiry of the original patent on omeprazole on July 6, 1999, to April 1, 2003 (calculated to the date of our submission to the Competition Bureau) was approximately \$537 million. This loss continued to mount by approximately \$502,000 per day, or \$3.5 million per week. Thus, if a generic version of omeprazole had been available in early 2002 (which is when we understand the first generic applicant would have been approved but for the existence of patents on the Register) the average employer's total drug benefit cost would have dropped by 1.6% on omeprazole alone. To the best of our knowledge, a generic omeprazole product was not available in Canada until June 2004.

In the case of paroxetine, Health Canada's review of one generic submission was complete in October 1999. Between October 31, 1999 and April 1, 2003, Drug Purchasers likely incurred a loss in the amount of approximately \$258 million.

Pharmaceuticals are the fastest growing component of Canada's healthcare system. We cannot tolerate these kinds of losses any longer. These losses are unnecessary expenditures and are a major drain on Canada's healthcare system.

Why is it that this government and others have taken so long to respond to Commissioner Romanow's comprehensive report? Why has this government proposed changes that merely tinker with the existing system, which is fundamentally flawed?

¹ The Romanow Report at 209.

Why has this government allowed brand name pharmaceutical companies to unfairly profit on the backs of consumers?

From the perspective of Canadian Drug Purchasers, the NOC Regulations are the *worst* possible system. The NOC Regulations are profoundly unfair to Drug Purchasers who have borne, and will apparently continue bear, the cost of *every single* unjustified 24-month delay mandated under the NOC Regulations. In this sense, the NOC Regulations have really been adopted on the back of all Canadian Drug Purchasers.

True Innovation vs. Legal Loophole Innovation

Consumers are generally not aware of the effect of patents on the cost of medicines. We support basic innovative research into new medicines. There is tremendous consumer benefit from the discovery of new medicines and we support a patent system that protects and encourages true innovation.

However, recently, pharmaceutical companies have expended tremendous resources on what is effectively marketing old wine in new bottles. This practice is best summarized by U.S. President George W. Bush, who in 2002 said as follows:

... some brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out.

We note that at the time of making this statement, President Bush announced a sweeping change to the drug patent laws, effectively preventing companies from obtaining multiple delays of approval of generic products.

Although the Canadian government is obviously aware of the manner in which the U.S. system was changed, it nevertheless chose to not follow the U.S. lead, and instead, proposed changes which still encourage the obtaining of unnecessary and unjustified delays. This is accomplished by allowing patents on minor changes to approved products to trigger additional pre-approval lawsuits. We have a number of concerns with the government's proposed amendments.

The Proposed Amendments Will Still Allow Unnecessary Delays

It appears to us that the government has only suggested changes to the rules regarding which patents can be added to the Patent Register, and when they can be added. Tinkering with the Regulations will necessarily leave room for the creation of additional loopholes and further delays.

For example, brand name companies will still be able to time the issuance and listing of patents in order to delay entry of generic products. This could be done through staggering patent applications (and even tinkering with the payment of fees to the Patent Office) to allow listing with supplemental submissions, obtaining and listing frivolous patents, obtaining and listing overlapping use patents, and obtaining and listing patents on different forms of the same medicine. In most cases, as has been the case under the current Regulations, such patents will not claim anything genuinely new and are simply the equivalent to packaging old wine in new bottles.

In addition, approval of generic drugs will continue to be delayed by “use” patents that are entirely irrelevant to the generic drug submission. In our view, a brand name company should not be permitted to prevent competition for a drug product because it has developed a new use for an old product. For example, Canadian consumers should not be deprived of access to affordable aspirin for use in the treatment of headaches merely because it has been discovered that aspirin is also an effective blood thinner.

The amended Regulations as currently drafted provide a number of obvious opportunities for continued delay in the approval of lower cost drugs. Put simply, this is unacceptable.

An easy way to stop unnecessary delays is to simplify the system. Early access to affordable medicine ought to be the fundamental consideration of the government in its consideration of the NOC Regulations. In our view, the best way to accomplish early access is to put a system in place that is founded on clear, specific rules.

One 24-Month Stay

In our view, the only way to stop unnecessary delays is to make the system simple: only require generic companies to address those patents on the Patent Register at the time the generic files its submission with Health Canada. This approach would add certainty and would not allow for evergreening of patents by brand name companies. As set out above, we understand that this is the route recently taken in the U.S. and we applaud the efforts of U.S. lawmakers in taking this approach.

The government has consistently ignored requests by consumers to remedy the problems associated with the NOC Regulations, and in addition has ignored the findings of the Romanow Report, which specifically considered the practice of evergreening as set out above. Indeed, Recommendation 41 of the Romanow Report is:

The federal government should immediately review the pharmaceutical industry practices related to patent protection, specifically, the practices of *evergreening* and the Notice of Compliance Regulations. This review should ensure that there is an appropriate balance between the protection of intellectual property and the need to contain costs and provide

Canadians with improved access to non-patented prescription drugs.²
[emphasis added]

In our view, the government's attempt to remedy the problems associated with the current operations of the NOC Regulations will not ensure an appropriate balance.

Drug Purchasers Are Entitled To Damages Caused by Unnecessary and Unjustified Delay in the Approval of Lower cost Pharmaceuticals

We note that the NOC Regulations contain a damages provision for generic companies who successfully defend a suit brought by the brand name company under the NOC Regulations. The generic is entitled to recover its lost profits for the period of time its market entry was inappropriately delayed. We understand, however, that this damages provision is completely ineffective and that no generic has yet been awarded damages, despite clear situations of unnecessary and unjustified delay.

In any event, we understand that the brand name company's profits earned during the exclusive marketing of its product are always greater than generic profits, and in every case the brand name company's profits earned during the improper market delay will be greater than the damages suffered by the generic company.

Thus, there is always a windfall to the brand name company, which corresponds directly to a loss, borne directly by Drug Purchasers who have paid higher prices when a lower-cost product should have been available.

Under the current regime and the proposed amendments, we have no legal remedy to recover our losses.³ Every dollar not spent by Drug Purchasers on increased drug costs is money otherwise available for our healthcare system.

In our view, if the government provided a system that compensated everyone, there would be less incentive for brand name companies to engineer delays in approval of lower cost generic products.

Proposed Amendments to the Food and Drug Regulations ("Data Protection")

As set out above, in our view the government's proposed regulatory amendments to the NOC Regulations fail to properly address the problem of patent evergreening, and will still allow unnecessary delays. This is particularly troubling in light of the government's proposed amendments regarding Data Protection, which will result in even longer delays in the market entry of generic drugs.

² The Romanow Report at 208.

³ We are advised by legal counsel that we would not be successful in obtaining our damages through a class action alleging anticompetitive behaviour as Canadian courts have not allowed these cases to proceed, see for example: *Chadha v. Bayer Inc.* 200 D.L.R. (4th) 309, at para. 41.

Commissioner Romanow, the Commissioner of Competition, President Bush and the U.S. Congress have all, among others, called for an end to evergreening. In contrast, there has been no public debate in Canada about data protection. Despite this, the government is proposing to lengthen the exclusivity period of brand companies from five to eight years. We understand that in many cases this will delay the entry of lower cost generic drugs at a cost of hundreds of millions of dollars per year.

This measure seems to counter the intent of the government in stopping unnecessary and unjustified delays in the market entry of safe and effective lower cost drug products.

We demand that the government maintain Data Protection at five years, as we understand is the case under the current regulatory regime.

Conclusion

We are concerned about the impact of the Regulations on the future of the Canadian healthcare system, and are angry that the government has not tackled this issue in any meaningful way. Changes to the proposed regulatory package must be made.

We welcome any opportunity to meet with you to discuss our comments specifically, or reform to the NOC Regulations generally.

Sincerely,

Canadian Pensioners Concerned Incorporated

Gerda Kaegi, President
10 Trinity Square
Toronto, ON M5G 1B1
Tel: 416.368-5222
Fax: 416.368-0443
Email: gerda.kaegi@sympatico.ca

National Union of Public and General Employees

James Clancy, National President
15 Auriga Drive
Nepean, ON K2E 1B7
Tel: 613.228-9800
Fax: 613.228-9801
Email: jclancy@nupge.ca

Congress of Union Retirees of Canada (“CURC”)

Larry Wagg, First Vice-President
2841 Riverside Drive
Ottawa, ON K1V 8X7
Tel: 613.521-3400

Fax: 613.521-0423
Email: curc@clc-ctc.ca

Canadian Health Coalition

Michael McBane, National Coordinator
2841 Riverside Drive
Ottawa, ON K1V 8X7
Tel: 613.521-3400, ext. 308
Fax: 613.521-9638
Email: mmcbane@clc-ctc.ca

Consumers' Association of Canada

Mel Fruitman, President and CEO
267 O'Connor Street, Suite 404
Ottawa, ON K2P 1V3
Tel: 613.238-2533
Email: fruitman@sympatico.ca

Alliance of Seniors

Al Gorlick, Chairman
50 Baldwin Street, Suite 210
Toronto, ON M5T 1L4
Tel: 416.260-3429
Fax: 416.348-0438
Email: allianceofseniors@bellnet.ca

National Pensioners and Senior Citizens Federation Incorporated

Art Field
Tel: 705.786-2778
Email: afield1@sympatico.ca

Ontario Society (Coalition) of Senior Citizens Organizations

Morris Jesion
Te: 416.785-7361
Email: ocsco@web.net