

**Notice of Proposed Regulations to
Amend Regulation 935 under the *Drug
Interchangeability and Dispensing Fee
Act* and Ontario Regulation 201/96 under
the *Ontario Drug Benefit Act***

BY
CANADIAN PENSIONERS CONCERNED, INC.
ONTARIO DIVISION

Prepared by Gerda Kaegi, Board Member

APRIL 2010

**Notice of Proposed Regulations to Amend Regulation 935 under the
Drug Interchangeability and Dispensing Fee Act and Ontario
Regulation 201/96 under the *Ontario Drug Benefit Act***

Canadian Pensioners Concerned, Inc., Ontario Division has a long history of engagement in the issues of access and pricing of prescription drugs both in Ontario and across the country. We have argued consistently that the fair cost of prescription drugs was severely affected by the changes to the patent regulations brought in by the Progressive Conservative government of the day in 1993. The patent life was extended significantly and the public's access to generic drugs was seriously compromised. The use of the legal system by the patent drug manufacturers to try to delay the expiry of their patents by adding additional and frivolous patents to their products was a further complication that we tried to address by taking a complaint to the Competition Bureau with a group of like-minded organizations.

We are very pleased that the government of Ontario is beginning to tackle the exponential rise in the cost of prescription drugs in the province. We are pleased that the government is prepared to put the needs of all purchasers of prescription drugs on an equal footing, rather than just look at its own economic costs. However, we are seriously disappointed that the major cost driver, the patent drug manufacturers, are not being challenged. Nearly 75 percent of the public cost of prescription drugs goes to the patent drug manufacturers the remainder to the generic drug makers, yet the generic drug makers provide the overwhelming amount of product to the pharmacies and thus, the public.

It is important to note that, when the patents of patented drugs were extended by the Mulroney government in 1987, the patent drug manufacturers promised that they would spend at least the equivalent of 10 percent of their marketing costs in Canada on research and development in this country. In their annual reports, the Patent Medicines Prices Review Board (PMPRB) noted that the 10 percent promised has not been met for the past eight years and indeed, the industry has rarely even come close. We must ask why these drug manufacturers are immune from meeting their contractual obligations. This sector is the basis of the high cost of prescription drugs in Ontario.

Why is the Government of Canada not forcing the Patent Drug manufacturers to meet their research and development obligations to Canada? Why is the Ontario Government silent on these issues?

Finally, we have never understood why the pharmacy business in Canada built its business model in recent years on the inclusion of generic drug manufacturers – **not patent drug manufacturers** – paying the pharmacy for shelf space! This is a questionable approach to have taken.

If generic drugs had the same share in Ontario that they have in the U.S. market, the cost of prescription drugs to the consumer would fall dramatically. This fact does not negate the need to end the practice of generic drug manufacturers paying druggists to stock their products.

Our comments on the proposed regulatory changes follows:

A. Professional Allowances

1. We support in principle the elimination of the "professional allowances" paid by the generic drug manufacturers to pharmacies in Ontario. We believe such practices are inappropriate and should never have been allowed.
2. We are concerned, however, about the need to ensure that there is truly open access for competing generic drugs to the retail pharmacy market. We are not sure that anything in the revised regulations will cover this concern.

B. Establishing a Fair Price

We believe that in order to establish a "fair" and "appropriate" price for the generic equivalent to a patent drug product, the real cost of creating the generic has to be taken in to account. To arbitrarily decide that the "fair" price is 25 percent of the price of the patent original is clearly indefensible.

- a) While the price of the patent drug is somewhat controlled when it first enters the country in that the proposed price is made in comparison to its price in other developed countries, that does not ensure, in fact, **that** price is reasonable or fair to the consuming public.

- b) Many of the recently patented drugs are just minor variations of older drugs ("me too drugs") but the new price is significantly higher. The newer drug is marketed heavily to physicians and the consumer. What is the government of Ontario doing to block entry of these drugs into the province? An action like that would bring down costs to everyone.
- c) We have tracked this issue for many years and we know that the patent drug companies throw legal barriers, court challenges and false patents in the way of generic manufacturers once they have stated that they will be bringing a generic version on line at the expiry of the original patent. Where are these costs to the generic accounted for in the decree of the "25 percent" price? Is the government of Ontario saying the real cost of manufacture is irrelevant?
- d) The same comparisons should be made between the costs of generics in Canada and the identical products in other developed countries. Are the patent regimes similar? Do the patent drug companies have access to the same costly delaying tactics that they have in Canada? These are important factors to be considered when setting prices.

C. Costs of Prescription Pharmaceuticals and Pharmacies

We believe that it is essential to control the fastest growing cost sector of the health care system, prescription drugs. We also believe that research and development bring important direct and indirect employment opportunities and ancillary benefits to Ontario. If the patent drug manufacturers spent more money in Canada on research, development and manufacturing, and less on marketing their products, we would all benefit. They committed to doing this in return for the extension of their patents; we should force them to honour that commitment.

The survival of the rural and small town pharmacies is also of concern and, whatever action the provincial government ultimately takes in this matter, their special business needs must be taken into account. Rural and small town pharmacies face different challenges than the urban stores, and the needs of their communities depend on their ability to survive in the business world.

We do not see any need for drugstores to stay open 24 hours a day – they are not generally open 24 hours a day in rural and small town Ontario. It used to be rare in urban centres. If prescription drugs are delivered, of course there should be a delivery charge.

We do not see a valid reason to force consumers to go to pharmacies for special services that up to this point are provided by their health care provider in order to improve the bottom line of pharmacies. This is just shifting one system of pay into another one without tackling the underlying issue – the pharmacy revenue base.

The policy issue of generic drug manufacturers paying druggists to stock their products is not an attack on pharmacists. It is an attempt to bring down an unnecessary cost factor in the overall cost of purchasing prescription drugs. We think that the manufacturers would not be unhappy in getting rid of these payments provided the competition they face in the market is fair. This is a challenge for the provincial government.

Finally, the patent drug manufacturers have, essentially, a monopoly for their products, where competition is extremely rare. This is where the major focus of public policy should be. The patent extensions granted in the 1980s have not served the public well. The Federal Government must undertake to reduce the unfair benefits received by the patent drug manufacturers. The Ontario Government should demand action from Ottawa to demonstrate its commitment to fair pricing of prescription drugs.