



Brief to the Standing Committee on Social Policy

on

Bill 102

An Act to amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act.

Submitted By:

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Bill 102: An Act to amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act.

We are Canadian Pensioners Concerned, Ontario Division; founded in 1969, part of a national voluntary organization of seniors which advocates on issues such as pensions, health care, housing and transportation. We are concerned not only about those matters which involve older citizens but about all of the factors which make for a just, caring, compassionate, civil society for all age groups. The issue of access and cost of prescription drugs has been of concern to our organization for many years.

We submitted a brief to the Drug Benefit Review in which we raised a number of concerns and provided some suggested solutions. Our response to Bill 102 will be based in part on our original view of what was wrong with the system and where we believed the province should go with new legislation.

We are strong supporters of Bill 102 and believe that it will be a step forward in preserving the viability and sustainability of our public and private health care system in Ontario. We realize that there will be groups opposing this legislation but we hope the government will move forward after careful consideration with all parties in the legislature and the public. The time to act is now – not a year from now.

We continue to call on the Provincial government to act in concert with the other provinces, Territories and the Federal government to end the abuse of the Federal Patent Drug Regulatory process by the patent drug manufacturers. We must stop the practice of “evergreening” patents through the manipulation of the current system. This practice has limited competition and thus kept the price of many drugs at an artificially high price. If the United States can take action against this practice we can too.

We are strong supporters of Bill 102, and thus will only raise issues of concern. In our Brief, we will address both parts of Bill 102 together (*Part I Amendments to the Drug Interchangeability and Dispensing Fee Act and Part II Amendments to the Ontario Drug Benefit Act*) when the articles are the same in their intent. We will then raise particular issues that relate only to either Part I or Part II.

A. The cost of prescription drugs to both the government and private payers whether individuals, employers or private insurance programs.

We strongly support the moves taken by the government in Bill 102 that will help slow down the exponential yearly increases in the costs of prescription medications over the last ten years. We recognize that part of the cost comes from the development of new technologies but that is not the focus of our concern. We know that **most of the “new”** patent drugs coming onto the market are **not really new** but they come in at a higher price than existing drugs and thus drive up the overall costs. We are concerned that these drugs will be added to the Formulary without providing any proven extra benefit to the public. Furthermore, decisions about the placement of drugs on the formulary, the utility and safety of the drugs are not made in an open and publicly accountable manner. It would be interesting if the Province would require that all drugs accepted for the Formulary would have to prove that clinical trials had taken place using existing drugs for the same conditions. Such is not the case today. Finally, we are concerned that the appropriate experts in the different fields of practice are not involved, and that evidence based best practices are not being fully considered.

Recommendation 1. The Advisory Committee to Evaluate Drugs will base its recommendations on stringent evidence based criteria. “New” copycat patent drugs must meet new benefit requirements in order to be listed on the formulary.

Recommendation 2. The decisions and the reasons for those decisions made by the Advisory Committee to Evaluate Drugs should be readily available to the public on a regular basis.

B. The Decisions of the Executive Officer [Part I, Section 12.2 (3), and Part II 11.6 (2)]

The denial of appeal from the decision or action of the Executive Officer under these sections.

We believe that there must be a process of appeal from a decision of the Executive Officer in relation to the listing on the formulary, the interchangeability status, the drug benefit price or the deleting of a drug from the formulary. We call for the creation of an Appeal Board, however, we believe that such a Board must be external to the Ministry of Health and Long Term Care, and appointed by Order-in Council. We would expect that a variety of specialists would be involved including Geriatricians.

Recommendation 3. We recommend that a special Appeal Board be established that would be composed of an external panel of experts with very clear criteria for grounds for appeal.

Part I

Amendments to the Drug Interchangeability and Dispensing Fee Act

C. Interchangeability and Off-Formulary Interchangeability

We support the ensuring of competition by providing for the interchangeability of generics with **both the same amounts of the same or similar active ingredients in the same or similar dosage form** as the patent drug. This will hopefully bring to an end the unfair benefits to the patent drug companies from their practice of evergreening patent drugs, which has blocked real market competition for years.

Off-formulary interchangeability will finally allow drugs that are not covered by the government's drug plan to be fully available in Ontario in lower-cost generic versions. This change will help employers who have drug plans for their employees, but it will also help people who don't have a drug plan and seniors in Ontario who have been prescribed drugs that are not covered by the ODB.

Recommendation 4. We support the new criteria for "interchangeability" including both the same amounts of the same or similar active ingredients in the same or similar dosage form.

Recommendation 5. We urge the government to carefully define the meaning of "similar" to ensure that it achieves the intent of the legislation.

D. Subsection 4 (5) Role of the dispensing Pharmacist

We have some concern about the use of the wording "may dispense" rather than "shall dispense" if there is a generic available. This would potentially leave the dispensing pharmacist to decide whether to provide the interchangeable product or not and thus subvert the intention of the legislation.

Recommendation 6. We would urge that the permissive language "may" be strengthened to "shall" unless special circumstances warrant otherwise, such as an instruction from the prescribing physician.

E. Issue of Rebates [Part I 4. Rebate 12.1 (1) and Part II Rebates etc. 11.5]

We totally support the prohibition of hidden rebates, whether monetary or benefits in kind, to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies. We believe that the pricing of drug products must be open and transparent to the government, taxpayers and consumers. It is not fair to taxpayers/consumers/patients that 40% of every dollar we spend on a generic drug is going to pharmacists in the form of an under-the-table payment.

From time to time there are media stories claiming that generic drugs are priced higher in Canada than in other jurisdictions. Well, now we know why and we are pleased that the government is going to put a stop to this practice.

We are concerned, however, that the Minister has indicated that he intends to allow “educational” spending by generic drug companies on pharmacists. If this is the case, then the government won’t have banned rebates, it will have simply changed the name.

It’s time to face facts. As Dr. Marcia Angell, former Editor of the New England Journal of Medicine, said in her 2004 book “The Truth About Drug Companies” - *Drug companies are not in the education business. If they were, they would sell their education programs, not give them away or pay people to accept them.* (page 151)

That’s true about both brand-name and generic drug companies.

We support the important role that pharmacists play in the health care system and are pleased that the government is more fully recognizing this role and increasing various payments for pharmacists in Bill 102.

Pharmacists should be fairly compensated for the important services they provide to patients. They should not have to rely on under-the-table “rebates” from drug companies.

Recommendation 7. We support the prohibition of the provision of rebates by and to any actor in the drug manufacturing, purchasing and distribution process.

F. We support the plan under **4. 12.1 Regulations (11) to clarify the meaning of “rebate”**. We recommend the development of a “Code of Conduct” that would be applied to all prescription drug manufacturers. If there are violations of that code then the penalties set out in the legislation should be applied.

Recommendation 8. A clear code of conduct should be established for drug manufacturers and those in the distribution and selling of prescription drugs that would clarify what is acceptable and unacceptable behaviour.

Part II Amendments to the Ontario Drug Benefit Act

G. Principles. Section 0.1

We are concerned by an over emphasis on economic considerations in the principles and believe that the health and welfare of the citizens must have primacy while recognizing that there are cost implications for the program. We have needs as human beings, as citizens who are, at the same time, taxpayers. We therefore suggest the following:

Recommendation 9. Part II, New Principle 1. Decisions for listing of drugs are to be made on the best clinical evidence available to meet the health needs of Ontarians. [The existing Principle 1 is already covered by the proposed principle #4]

H. Section 1.1 (2) (j) Payment to Pharmacies for professional services.

We support the payment for professional services to pharmacists that go beyond the simple dispensing fee. Under the new legislation the potential role of the professional pharmacist to advise the consumer will be expanded. However, we believe that such payments must be based on clear criteria and subject to a special audit. It is important to the consumer that they can be assured that payments for professional services are for services that have actually been provided.

Recommendation 10. We support the recognition of the additional role for pharmacists under this legislation through additional payments. At the same time, we believe that these payments must be for specifically defined services and subject to surprise audits – similar to those done on physicians' billing practices.

Summary of Recommendations

1. The Advisory Committee to Evaluate Drugs will base its recommendations on stringent evidence based criteria. “New” copycat patent drugs must meet clear new benefit requirements in order to be listed on the formulary.
2. The decisions and the reasons for those decisions made by the Advisory Committee to Evaluate Drugs should be readily available to the public on a regular basis.
3. We recommend that a special Appeal Board be established that would be composed of an external panel of experts with very clear criteria for grounds for appeal. (re.Executive Officer)
4. We support the new criteria for “interchangeability” including both “the same amounts of the same or similar active ingredients in the same or similar dosage form.”
5. We urge the government to carefully define the meaning of “similar” to ensure that it achieves the intent of the legislation.
6. We would urge that the permissive language “may” be strengthened to “shall” unless special circumstances warrant otherwise, such as an instruction from the prescribing physician. (Role of Pharmacist)
7. We support the prohibition of the provision of rebates by and to any actor in the drug manufacturing, purchasing and distribution process.
8. A clear code of conduct should be established for drug manufacturers and those in the distribution and selling of prescription drugs that would clarify what is acceptable and unacceptable behaviour.
9. Part II, Principle 1. Decisions for listing of drugs are to be made on the best clinical evidence available to meet the health needs of Ontarians. [The existing Principle 1 is already covered by the proposed principle #4]
10. We support the recognition of the additional role for pharmacists under this legislation through additional payments. At the same time, we believe that these payments must be for specifically defined services and subject to surprise audits – similar to those done on physicians’ billing practices.