

Bill 102:
Ontario's Prescription for Drug Cost Savings
and Greater Transparency

Remarks by

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GENERIC DRUGS.



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Canadian Generic Pharmaceutical Association

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Thank you and thank you to The Economic Club of Toronto for inviting me to be here today to take part in this series on Bill 102, The Transparent Drug System for Patients Act.

As many of you will know, CGPA is the national association that represents Canada's generic pharmaceutical industry.

I'd like to start off today with some basic information about generic medicines because even though generic drugs are dispensed to fill fully 44 percent of all prescriptions in Canada, that's 170 million prescriptions last year (57 million generic prescriptions in Ontario), many Canadians do not know about generic drugs or understand the difference between brand-name and generic drugs.

Generic drugs are low-cost versions of brand-name drugs. Generics are produced by several manufacturers once the patents expire on the brand-name versions.

Brand-name drugs have 20 years of patent protection. During that time, only the patent holder can produce the drug. After that, other manufacturers can apply to Health Canada to produce and market generic versions.

There are no differences as far as quality, purity, effectiveness, and safety between generic drugs and higher-priced brand-name drugs.

All drugs sold in Canada must be approved by Health Canada. Each product must meet the strict regulations established by *The Food and Drugs Act*. Both generic and brand-name drugs are subjected to the same rigorous standards.

Active ingredients in a generic drug and brand-name drug must meet the same scientific norms and standards set by Health Canada.

When applying to sell a generic equivalent of a brand-name drug, the manufacturer must prove that the product is as safe and effective as the brand version.

Generic manufacturers must also prove that the active ingredients in the medicine are as pure, dissolve at the same rate, and are absorbed in the same manner as the original product.

So, there is no difference in the quality and safety of generic and brand-name drugs.

Next I would like to speak briefly about Ontario's generic pharmaceutical industry.

Dr. Roger Martin of the Rotman School of Business at the University of Toronto speaks of the importance of industry clusters. I'd like to tell you something about the generic industry cluster in Ontario, which is one of the largest and most impressive groupings of generic drug companies in any jurisdiction in the world.

The generic pharmaceutical industry employs more than 7,500 Ontarians directly in well-paid, highly skilled jobs in its research and development and manufacturing facilities.

Thirteen of CGPA's member companies are located here in Ontario, largely in the Greater Toronto Area.

The industry spends approximately 300 million dollars annually on research and development in Ontario.

In fact one of CGPA's member companies, Toronto-based Apotex, is the largest R&D spender among all pharmaceutical companies in Canada – brand or generic.

According to Research Infosource's 2005 annual list of the top 100 corporate R&D spenders in Canada, Apotex spent 173 million dollars on R&D, which equals 20 percent of the company's sales.

On average, generic drug companies are spending close to 15 percent of their revenues on research and development. This is nearly twice as large as the eight percent spent by brand-name companies as reported by the Patented Medicines Pricing Review Board.

The reason for this is because, unlike most brand-name drugs, which are shipped into Canada and Ontario, virtually all generic drugs sold in Canada are made in Canada. And the majority of those are made right here in Ontario.

These facts are important as we consider the potential economic impact of Bill 102.

I'd like to turn now to health-care savings.

I have already demonstrated earlier in my talk that generics are the same quality as their brand-name equivalents. The facts on savings are just as clear. Generic pharmaceuticals are dispensed to fill fully 45 percent of all prescriptions in Ontario – that figure encompasses both the public and private sector – yet account for only 17 percent of the 6.7 billion dollars spent annually on prescription drugs.

For the public or government sector, generics fill more than 50 percent of all prescriptions paid for by the Ontario government yet account for only 20 percent of the 3.5 billion dollars spent by the Province on prescription medicines.

Looked at another way, the average cost of a generic prescription is about 23 dollars while the average cost of a brand-name prescription is about 62 dollars.

As these figures clearly demonstrate, generic drugs offer excellent value for money and play a key role in the affordability and ongoing sustainability of the health-care system.

By increasing the use of lower-cost generic equivalents, there will be more money available for other priorities for our health-care system such as supporting pharmacy, hiring nurses, reducing waiting times and investing in new, life-savings technologies, including new pharmaceutical products.

As well, saving money by using more generic medicines is a far better way to reduce costs than cutting benefits or asking seniors and social assistance recipients to pay more for their prescription drugs.

We believe that the generic industry can do even more. And Bill 102 takes a number of important steps in ensuring that the generic pharmaceutical industry can increase its contribution to affordable health care in both the public and private sectors in this Province, and its significant investments in the Ontario economy.

The proportion of generics to the total market is actually much lower in Canada than it is in the United States, where generics are used to fill more than 50% of all prescriptions.

We think generic utilization needs to be increased and Bill 102 will help to do that for Ontarians. That is why CGPA supports Bill 102.

In particular, we support the announced initiatives to provide greater access to lower-cost generic drugs for those Ontarians that are not covered by the Ontario government's drug plan.

One of these initiatives, called off-formulary interchangeability or OFI, will save Ontario businesses and families more than 30 million dollars in the first year alone.

These savings calculations are based on the differences in prices currently charged by brand-name and generic companies for drugs affected by OFI.

Unlike virtually every other jurisdiction in North America, Ontario's current rules do not allow employers and consumers clear access to lower-cost generic drugs in the way that was originally intended in the legislation.

These current rules also penalize Ontario seniors and social assistance recipients who need medications that are not covered by the government's drug plan.

At the stakeholder briefing on April 13 when the government's proposals were announced, representatives of the Drug System Secretariat noted that every major employer that provided comment during consultations on the government's proposed changes asked for the government to implement OFI.

These stakeholders included the Employer Committee on Health Care in Ontario (ECHCO), and Greenshield, which operates the drug benefit plans for the "Big Three" automakers.

I want to point out that ALL brand-name drugs that would face full competition in the Ontario private sector under OFI are off-patented products that have already enjoyed the benefit of 20-year patents.

Those patents have now expired, generics have entered the market and it is time for Ontario employers and consumers to benefit from lower prices generated by generic competition.

When brand-name drug companies oppose the government's interchangeability proposals they are in effect demanding that Ontario employers and consumers continue to pay for higher-priced brand-name drugs, rather than face competition from equivalent lower-cost generics and this is even after patents have expired.

This is an important point. There is absolutely nothing in Bill 102 that in anyway erodes intellectual property protection for brand-name drugs.

And even though Bill 102 does not affect intellectual property protection, this issue has crept into the debate on Bill 102 and I want to address it.

Intellectual property protection is set by federal law and is based on international trade agreements.

CGPA and Canada's generic pharmaceutical industry support patent rights and the right of any pharmaceutical company – brand or generic – to recoup their investments and turn a profit to help grow and sustain their business.

However, we should not buy into the false argument that the only way to encourage innovation is by granting ever-longer periods of government sanctioned and enforced market monopolies.

This approach completely ignores the critical role that competition plays in encouraging innovation, not only in the pharmaceutical sector, but in all sectors of our economy.

We have heard rhetoric from the brand-name pharmaceutical industry since Bill 102 was introduced in mid-April. We have heard claims that Bill 102 will threaten investment by brand-name drug companies.

We have heard from representatives of the brand-name industry that Bill 102 will cost the industry 500 million dollars. In my estimation and given the actual practical implications of the provisions in the government's proposals, this number is simply not defensible.

I suggest that the brand-name industry tone down the rhetoric.

The interchangeability rules of Bill 102 are good for the economy. They will lower drug costs and they will provide healthy competition for brand-name companies for their off patent products.

Now, my final comments will address Canada's generic pharmaceutical industry's support for the Ontario government's desire as stated in Bill 102 for greater transparency in the drug reimbursement system.

The Ontario government and, frankly, other governments in Canada and around the world believe that the reimbursement system for generic pharmaceutical products must be more transparent for taxpayers and patients.

As Marc Kealey, CEO of the Ontario Pharmacists' Association said earlier this month in his remarks on Bill 102 to the Economic Club of Toronto, "We have to move forward. If there is one principle we have to come together on the same page about, it is that the status quo on the drug system is not acceptable and not sustainable."

CGPA agrees. This is simply the new reality.

In Quebec, generic pharmaceutical companies are currently facing more than three billion dollars in legal liability in a class-action lawsuit for allegedly providing rebates to their pharmacy customers. As well, several generic companies are being legally pursued on the same matter by the government drug agency RAMQ. These situations must be fixed.

Quebec's Bill 130 passed in December 2005 deals with rebates and tries to bring greater clarity to what is acceptable. It provides that some payments from generic companies to pharmacists will be authorized. CGPA is supporting those changes.

There has been concern raised in the pharmacy sector about the government's proposed ban on rebates and professional allowances in Bill 102.

In a speech to the Ontario Pharmacists Association annual meeting on May 13, Minister Smitherman clarified that some payments from generic companies in the form of educational or professional allowances would be allowed up to a limit of 20 percent of generic sales.

CGPA member companies understand the concerns of pharmacy with the proposed changes. Our companies also recognize the key role that pharmacists and the pharmacy sector play in the health-care system. We are pleased to see that in Bill 102, pharmacists will finally be recognized for more of the important services they provide to patients.

On the question of rebates or allowances, we are asking for clear rules. We also need to put in perspective our industry's ability to fund these payments.

As I said earlier, generic drugs account for only 17 percent of the nearly seven billion dollars spent annually for prescriptions drugs in Ontario and fill 45 percent of all prescriptions.

This means that more than half the time a pharmacist is dispensing a drug or counselling a patient he or she is doing so for a brand-name drug. Yet, the brand-name companies provide minuscule support to pharmacy in comparison to generic companies.

The generic pharmaceutical industry has only 17 percent share as measured by revenues. If the government proceeds with the major price decrease of approximately 20 percent for generic medicines that it has announced, then our revenue base will fall even more.

I should note that several of our member companies have argued forcefully earlier this week before the Social Policy Committee on the need to maintain fair prices for generics.

There must be some flexibility in generic reimbursement prices, particularly for some of the new, expensive products such as biopharmaceuticals.

If prices are set too low, generic companies will not be able to produce these medicines and provide savings to the health-care system.

However, if generic prices are cut then no one can expect the Ontario generic industry to continue to support pharmacy at the same level as it does today under these circumstances. It is simply not financially possible.

It is our goal to work with the government and our pharmacy and wholesaler partners on the issues of pricing, rebates and allowances to develop rules including a new code of marketing conduct, that will achieve the government's goal of full transparency while also ensuring the long-term viability and sustainability of all players in the generic pharmaceutical value chain including pharmacy and the generic drug industry.

Before concluding, I must stress that work needs to continue on the implementation of the regulatory and policy aspects of the Ontario government's overall proposals, since much of the final policy will be determined by regulation.

We call on the government to continue its consultations with all stakeholders.

Subject to this caveat we believe that it is important for our industry, for pharmacy, for the public health-care system, for every employer that provides a drug benefit plan for its employees, and for Ontario patients that Bill 102 be passed.

And that is why we are supporting Bill 102.

Thank you.

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