



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

THE "15-YEAR RULE:" THE OLD FIGURES NO LONGER HOLD UP

The province of Quebec's "15-year rule" is intended to extend brand name companies' market monopolies beyond the periods prescribed under the Canadian Patent Act, in order to keep jobs and investments in the province. Unique to Quebec, this rule requires the prescription drug insurance plan to reimburse the price of the original drug, even after their patents have expired and less expensive generic equivalents have become available. **The old figures:** a cost-benefit study of the "15-year rule" published in 2005 concluded that this rule should be maintained, as its brought in \$12 million more than it cost (income exceeding costs to the government). **To summarize these calculations:**

- Cost to the government: \$25 million (higher drug costs)
- Income for the government: \$37 million (taxes and income taxes resulting from economic spin-offs from the brand pharmaceutical industry)

PRESENT DAY COST BENEFIT ANALYSIS

Today, costs significantly exceed benefits: if a cost-benefit analysis of the "15-year rule" were conducted today, based on updated 2005 analyses, maintaining the rule could not be justified.

The CGPA conducted an updated evaluation of the rule's true impact on the cost of the prescription drug insurance program (higher drug costs). **Result:** in 2009, **the government lost out on potential savings in the order of \$120 million.** This is four times more than in 2005 (\$25 million)! **Reasons for this cost explosion? Mainly:**

- Increased use of prescription drugs;
- Significant reduction in the price of generic drugs since

2008;

- Appearance of "big sellers" on the list of drugs protected by the rule;
- Increase in the price of brand pharmaceuticals.

And the cost is expected to rise significantly over the coming years: the cumulative cost could be close to one billion dollars within five years.

Take for instance the case of the Atorvastatin molecule (better known under the brand name Lipitor). As of this summer, on this one medication alone, the government of Quebec will be foregoing — if it maintains its "15-year rule" — potential savings estimated at \$10 million per month for approximately 20

months, for a total of \$200 million! The CGPA is not alone in maintaining that the impacts of the "15-year rule" warrant constant and strict monitoring. Other proponents include committees established by the government of Quebec:

- Task force on the financing of the public health care system (chaired by Claude Castonguay) in 2008;
- Committee on the relevance and feasibility of a public prescription drug insurance program in Quebec (chaired by Claude Montmarquette) in 2001;
- These new evaluations of reductions in both expenditures and income are not only necessary, they are urgently required.

PHARMACEUTICAL INDUSTRY TRENDS - 2010 AND BEYOND

While the presence of the generic drug industry in Quebec is growing significantly, the brand pharmaceutical industry is experiencing a major reduction: fewer jobs and less research and development in Quebec.

Direct jobs:

- Down 20% since 2005 in the brand pharmaceutical industry in Quebec (from 11,300 to 9,200).
- Up 85% in the generic drug industry (from 2,600 to 4,800).

Research & Development:

- In 2008, for the first time since the year 2000, R&D spending by brand pharmaceutical companies was lower in Quebec than in Ontario (source: PMPRB).
- Between 2006 and 2008, Quebec's share of R&D spending by these companies in Canada dropped from 48.6% to 43.3%.