

The Real Story Behind Big Pharma's R&D Spending in Canada

Canadian Generic Pharmaceutical Association

2008

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

Canadian Generic Pharmaceutical Association

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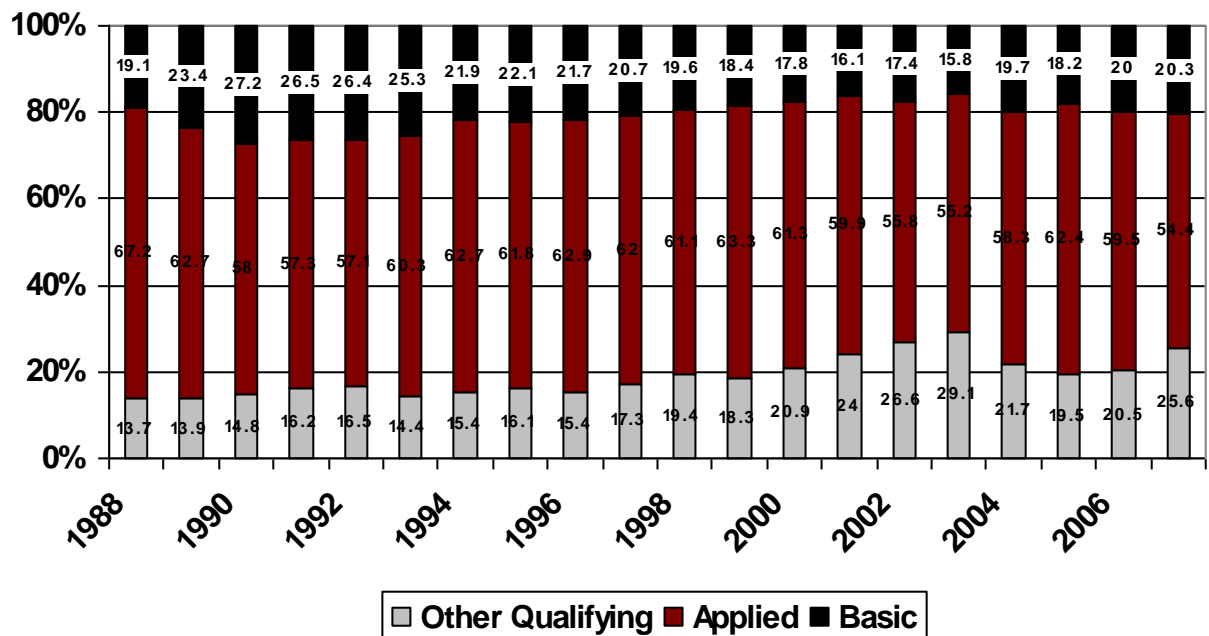
Big Pharma breaking its R&D spending commitment to Canadians

With the adoption of the 1987 amendments to the Patent Act (Bill C-22), Canada's brand-name pharmaceutical industry made a public commitment to increase their annual domestic research and development (R&D) expenditure to 10% of Canadian sales revenue.

The 2007 Annual Report of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are continuing to break their promise to Canadians. For the seventh consecutive year, Big Pharma's domestic R&D-to-sales ratio has fallen below the level the industry promised when the Mulroney Government passed Bill C-22.

Pharmaceutical patentees spent only 8.3% of their Canadian revenues on research and development in 2007, below the 10% threshold the industry committed to in 1987.¹

R&D Expenditure by Type of Research, 1988-2007²



Only 2% of Canadian sales revenue spent on basic research

Patentees reported spending \$259 million on basic research in 2007. This represents just one-fifth of their current domestic R&D expenditure, or 2% of their Canadian sales revenue.³

¹ Patented Medicine Prices Review Board – Annual Report 2007, page 43

² Patented Medicine Prices Review Board – Annual Report 2007, page 44

³ Patented Medicine Prices Review Board – Annual Report 2007, page 44

Clinical trials account for nearly 80% of applied research

Applied research is directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials and clinical trials. Patentees reported spending \$688.2 million on applied research, representing 54.4% of Big Pharma's domestic R&D expenditure. Clinical trials accounted for 78% of the applied research expenditure.⁴

Other qualifying research – includes drug regulation submissions, bioavailability studies and Phase IV clinical trials – accounted for the remaining 25.6% of the applied research expenditure in 2007.⁵

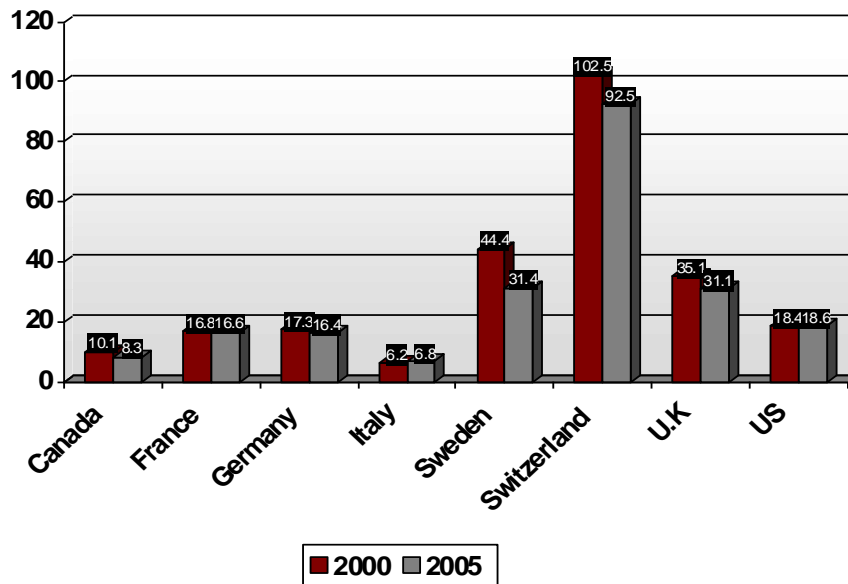
Canada's pharmaceutical R&D-to-sales ratio second worst of all countries

The PMPRB's 2007 Annual Report also shows that the ratio of R&D to domestic sales in Canada remains well below values in the United States and Europe.

In 2000, the Canadian ratio was 10.1%. Only Italy (6.2%) had a lower ratio in that year. Switzerland had the highest ratio at 102.5%, followed by Sweden at 44.4%. France, Germany and the U.S. were in the 16% to 18% range, while the U.K. was more than double (35.1%).

A very similar pattern emerges in the ratios for 2005. Italy (6.8%) remained at the bottom of the range, with Canada second lowest at 8.3%. Ratios in all other comparator countries remained well above Canada's ratio.⁶

R&D-to-domestic-sales ratios, Canada and 7 Comparator countries, 2000 and 2005⁷



⁴ Patented Medicine Prices Review Board – Annual Report 2007, page 44

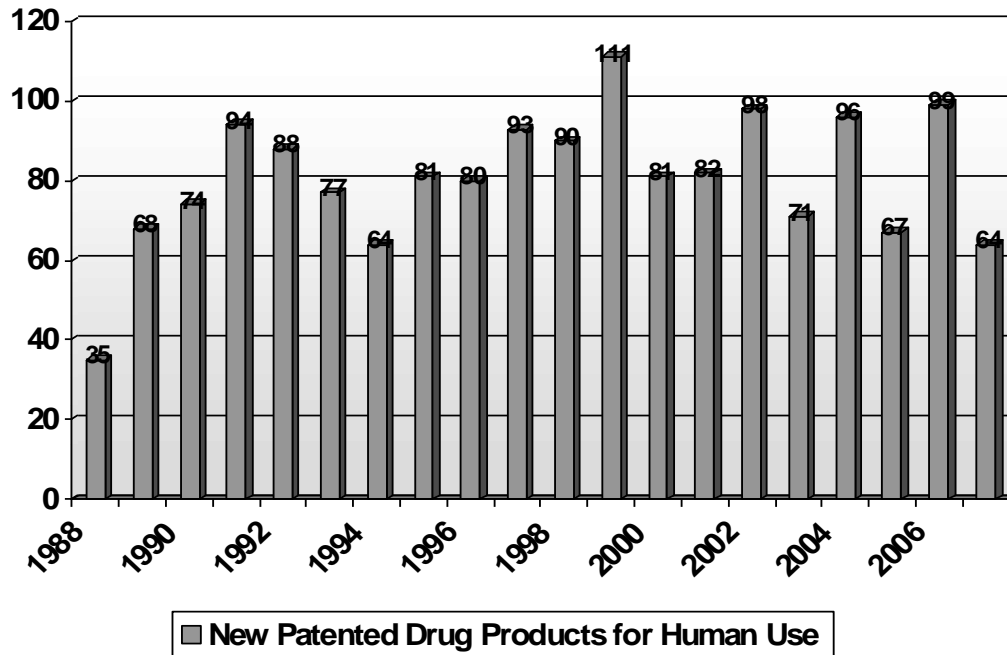
⁵ Patented Medicine Prices Review Board – Annual Report 2007, page 44

⁶ Patented Medicine Prices Review Board – Annual Report 2007, page 46

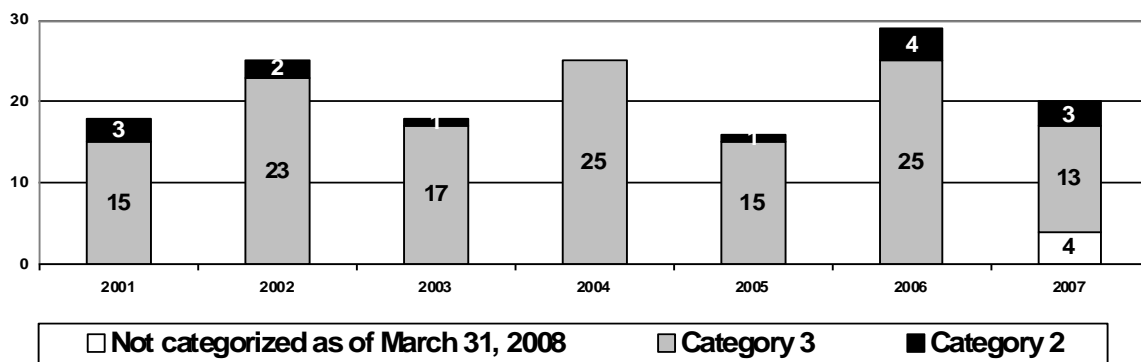
⁷ Patented Medicine Prices Review Board – Annual Report 2007, page 46

Most “new” drugs not truly innovative

There were 64 new patented drug products, or DINs (Drug Identification Numbers), for human use introduced in 2007. Some are one or more strengths of new active substances (NAS) and others are new presentations of existing medicines.⁸



In 2007, there were 20 new active substances.⁹ Of these, only 3 were in Category 2, which the PMPRB defines as “one that provides a breakthrough or substantial improvement”.¹⁰ The majority (13 new active substances) were in Category 3, which the PMPRB states “provide moderate, little or no therapeutic advantage over comparable medicines.”¹¹ The remaining 4 new active substances were not categorized as of March 31, 2008.



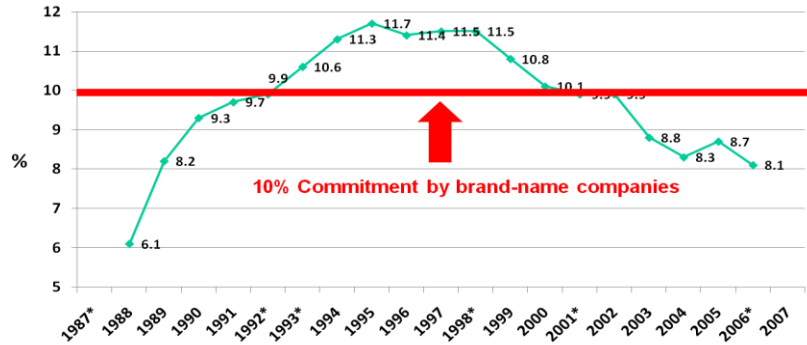
⁸ Patented Medicine Prices Review Board – Annual Report 2007, page 10

⁹ Patented Medicine Prices Review Board – Annual Report 2007, page 10

¹⁰ Patented Medicine Prices Review Board – Annual Report 2007, page 12

¹¹ Patented Medicine Prices Review Board – Annual Report 2007, page 12

R&D-to-Sales Ratio by Pharmaceutical Patentees, 1988-2006



1987	1992	1993	1998	2001	2006
Bill C-22	Bill C-91	PM(NOC) Regs	Amendments to PM(NOC) Regs	Bill S-17	Data Exclusivity (8.5 Years)

History of Increased Market Monopolies for Brand-Name Drug Companies in Canada

1987 – Bill C-22

Significant changes are made to the *Patent Act* in favour of the brand-name pharmaceutical industry, including an extension of patent terms for new drug products to 20 years from 17 years and limitations on the compulsory licensing regime for pharmaceutical patents. The Patented Medicine Prices Review Board (PMPRB) is established to monitor prices of patented medicines and R&D spending in Canada by brand-name drug companies.

1992 – Bill C-91

The compulsory licensing regime for pharmaceuticals is abolished, and the framework is provided for the new *Patented Medicines (Notice of Compliance) Regulations* of the *Patent Act*.

1993 – Introduction of Patented Medicines (Notice of Compliance) Regulations

These Regulations include a 30-month automatic stay provision (later reduced to 24 months) that provided brand-name companies with the means to delay the market entry of generic competition without the burden of proof. In addition, the Regulations contain loopholes that allowed for systematic abuse of the patent system by brand-name pharmaceutical industry to prolong their market monopolies – a practice known as evergreening.

1994 – Data Exclusivity

Changes to Food and Drugs Act to introduced five years of data exclusivity to benefit brand-name drug companies and comply with NAFTA.

1998 – Amendments to Patented Medicines (Notice of Compliance) Regulations

Amendments are made to the PM(NOC) Regulations but these fail to curb evergreening practices.

2001 – Bill S-17

Extends the terms of certain Old Act patents under Bill C-22 to 20 years from the date their applications. As a result, twenty-five commercially significant drugs benefit from a patent term extension

2006 – Data Exclusivity (8.5 Years) and Amendments to PM(NOC) Regulations

After 13 years of evergreening tactics by brand-name drug companies to unfairly extend market monopolies, amendments are introduced to limit the practice of evergreening. Unnecessary trade-offs were granted to the brand-name pharmaceutical industry, including an extension of Data Exclusivity to 8.5 years (8 years plus six months paediatric exclusivity) and the gutting of the section 8 damages provisions of the PM(NOC) Regulations.

2008 – Amendments to Patented Medicines (Notice of Compliance) Regulations

Federal government brings in changes to overrule a Supreme Court decision that found generic manufacturers should never have had to address irrelevant patents for drugs, even those patents that were listed prior to the 2006 changes to the PM(NOC) Regulations. The changes will delay generic market entry for some products and add to Canadians' prescription drug bills.

Increased market monopolies have not resulted in increased R&D spending

This data proves that more than 20 years of concessions to the brand-name pharmaceutical industry by the Government of Canada, including Bill C-22, Bill C-91 (which brought in the *Patented Medicines (Notice of Compliance) Regulations*) and Bill S-17, have had limited impact on research and development in Canada.

Despite this evidence, in October 2006 the Government of Canada again increased monopoly rights for brand-name companies through regulatory amendments to “data exclusivity” provisions of the *Food and Drug Regulations*.

The October 5, 2006 amendments to the *Food and Drug Regulations* establish yet another regime to provide brand-name drug companies with an 8.5 year (8 years plus 6 months pediatric exclusivity) ban on competition, even for non-patented drugs.

Canada’s pre-October 5, 2006 data protection regime of five years was in full compliance with international trade agreements such as the North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and should have been left as it was.

Generic pharmaceutical R&D spending in Canada outpaces Brands

The generic industry spends approximately \$615 million annually on research and development in Canada. In fact, one of CGPA’s member companies, Toronto-based Apotex, is the largest R&D spender amongst all pharmaceutical companies in Canada – brand or generic.

According to Research Infosource’s 2007 annual list of the top 100 corporate R&D spenders in Canada, Apotex spent \$179 million on R&D, which equals 17.6% of the company’s sales.¹²

What is also significant about these figures is that generic pharmaceutical companies make these investments on sales of \$4.1 billion in Canada¹³. The remainder, or \$15.2 billion of the \$19.3 billion spent annually on prescription drugs in Canada, is spent on brand-name drugs.¹⁴

Even setting aside the significant savings that generic pharmaceuticals bring to Canada’s health-care system, from purely an employment and investment perspective, it is an indisputable fact that a dollar spent on a generic drug results in more jobs, more investment in R&D, and more investment in pharmaceutical manufacturing capacity in Canada than a dollar spent on a brand-name drug.

(Please see Chart on Page 6)

¹² RESEARCH Infosource Inc. – Canada’s Top 100 Corporate R&D Spenders, 2007

¹³ IMS Health Canada – 12 months ending March 2008

¹⁴ IMS Health Canada – 12 months ending March 2008

Pharmaceutical Industry Investment in Canada: Generic vs. Brand

Canadian Sales

Total annual spending on prescription drugs:	\$19.3 billion
Brand:	\$15.2 billion (78.6%)
Generic:	\$4.1 billion (21.4%)

Total number of prescriptions filled

	430 million
Brand:	218 million (50.8%)
Generic:	212 million (49.2%)

Source: IMS HEALTH - 12-months ending March 2008

Employment in Canada

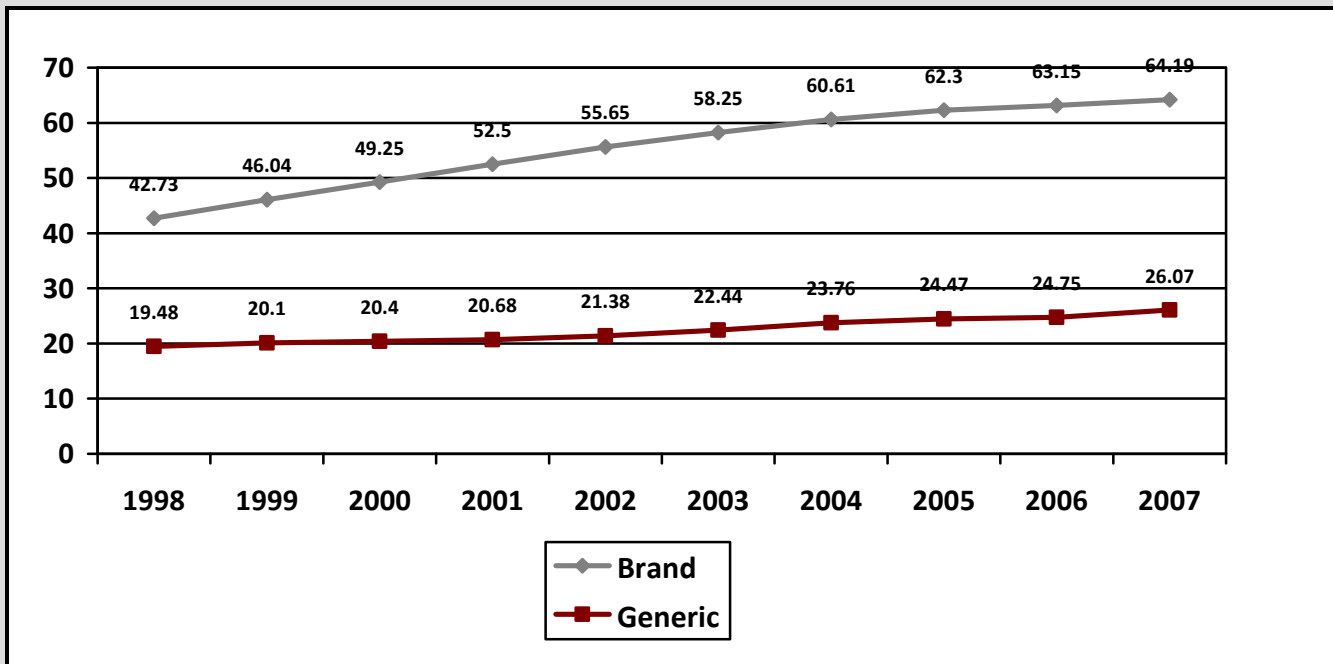
Brand:	22,000 (Source: Rx&D)
Generic:	11,000

Research and Development Spending in Canada

Brand:	\$1.3 billion/8.3% of sales (Source: PMPRB)
Generic:	\$615 million/15% of sales

Average Cost Per Prescription in Canada: Brand vs. Generic

Source: IMS Health



Conclusions

From a public policy perspective, the most important and relevant question regarding the pharmaceutical intellectual property regime is whether or not it is serving the interests of Canadians.

More than 20 years after the introduction of Bill C-22, which gave brand-name drug companies longer periods of market monopoly, and 15 years after the introduction of the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act*, it is clear that years of concessions to the multinational brand-name pharmaceutical industry by the Government of Canada has not served the interests of Canadians.

- For seven consecutive years, pharmaceutical patentees have failed to meet the minimum commitments for R&D spending in Canada that they made to the Canadian government when their state-sanctioned and enforced market monopolies were increased in 1987. Pharmaceutical patentees spent only 8.3% of their revenues on research and development, below the 10% threshold the industry committed to in 1987.
- Patentees reported spending \$259 million on basic research in 2007, representing only 20.3% of their domestic R&D expenditure, or 2% of their Canadian sales revenue.
- Relative to other countries, increased pharmaceutical patent protection has not resulted in more research and development in Canada. In 2005, of all countries examined by the PMPRB, only Italy (6.8%) had a lower R&D-to-sales than Canada (8.3%). Ratios in all other comparator countries were well above Canada's ratio.
- Of the 151 new active substances introduced in Canada from 2001 to 2006, only 14 (less than 10%) were categorized by the PMPRB as a "breakthrough" or "substantial improvement" over existing drug products.
- Given its enormous annual sales in Canada, brand industry job creation is quite low (22,000 jobs on \$15.2 billion in sales). In contrast, the generic industry employs more than 11,000 Canadians on just \$4.1 billion in sales.