

THE **REAL STORY** BEHIND **R&D SPENDING** BY



BRAND-NAME DRUG COMPANIES IN CANADA



**GENERIC DRUGS
SAME QUALITY
LOWER PRICE**

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION - 2010

4120 Yonge St., Suite 409 | Toronto, Canada, M2P 2B8 | 416-223-2333 | www.canadiangenerics.ca

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BRAND-NAME DRUG COMPANIES BREAKING 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 its annual domestic research and development (R&D) expenditure to 10% of Canadian sales revenue.¹

The 2009 Annual Report of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are continuing to break their promise to Canadians. For the ninth consecutive year, pharmaceutical patentees' domestic R&D-to-sales ratio is below the level the industry promised when the Government of Canada passed Bill C-22.

TOTAL R&D EXPENDITURES AND R&D-TO-SALES RATIOS - 1988 TO 2009²

Year	Companies Reporting	TOTAL R&D Expenditures (\$M)	% Change From Previous Year	TOTAL SALES Revenue (\$M)	% Change From Previous Year	% R&D-TO-SALES RATIO
2009	81	1272.0	-2.9	17,519	4.5	7.5
2008	82	1310.7	-1.1	16,316.7	2.0	8.1
2007	82	1325.0	9.5	15991.0	7.3	8.3
2006	72	1210.0	-9.1	14902.0	4.7	8.1
2005	80	1234.3	5.5	14231.3	0.5	8.7
2004	84	1170.0	-2.0	14168.3	4.0	8.3
2003	83	1194.3	-0.4	13631.1	12.8	8.8
2002	79	1198.7	13.0	12081.2	12.5	9.9
2001	74	1060.1	12.6	10732.1	15.3	9.9
2000	79	941.8	5.3	9309.6	12.0	10.1
1999	78	894.6	12.0	8315.5	19.2	10.8
1998	74	798.9	10.2	6975.2	10.9	11.5
1997	75	725.1	9.0	6288.4	7.4	11.5
1996	72	665.3	6.4	5857.4	9.9	11.4
1995	71	625.5	11.5	5330.2	7.5	11.7
1994	73	561.1	11.4	4957.4	4.4	11.3
1993	70	503.5	22.1	4747.6	14.0	10.6
1992	71	412.4	9.6	4164.4	6.9	9.9
1991	65	376.4	23.2	3894.8	18.1	9.7
1990	65	305.5	24.8	3298.8	11.0	9.3
1989	66	244.8	47.4	2973.0	9.4	8.2
1988	66	165.7	-	2718.0	-	6.1

Pharmaceutical patentees spent only 7.5% of their Canadian revenues on research and development in 2009, below the 10% threshold the industry committed to in 1987.³ This is the lowest ratio reported by pharmaceutical patentees in the past 20 years.

FOOTNOTES:

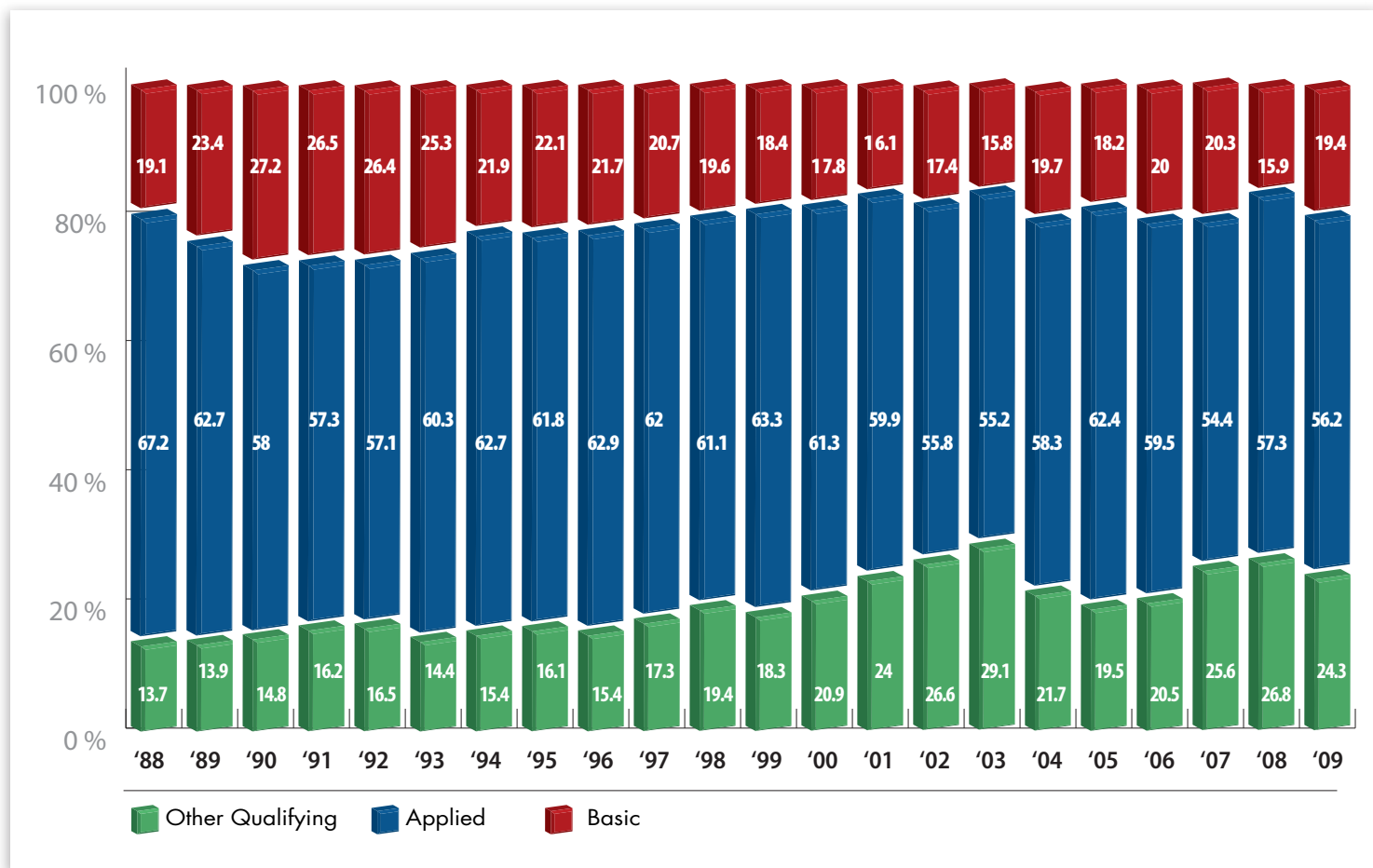
1. Patent Medicine Prices Review Board - Annual Report 2009, page 37
2. Patent Medicine Prices Review Board - Annual Report 2009, page 36
3. Patent Medicine Prices Review Board - Annual Report 2009, page 36



ONLY 1.8% OF CANADIAN SALES REVENUE SPENT ON BASIC RESEARCH

Patentees reported spending \$237.1 million on basic research in 2009, representing 19.4% of current R&D expenditure. This represents just 1.8% of their Canadian sales revenue.⁴

R&D EXPENDITURES BY TYPE OF RESEARCH FROM 1998 TO 2009⁵



CLINICAL TRIALS ACCOUNT FOR 76.8% OF APPLIED RESEARCH

As defined by the PMPRB, 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 \$685.3 million on applied research, representing 56.2% of current R&D expenditure. Clinical trials accounted for 76.8% of applied research expenditures.⁶

Other qualifying research, which includes drug regulation submissions, bioavailability studies and Phase IV clinical trials, accounted for the remaining 24.3% of the research expenditure in 2009.⁷

FOOTNOTES:

- 4. Patent Medicine Prices Review Board - Annual Report 2009, page 38
- 5. Patent Medicine Prices Review Board - Annual Report 2009, page 38
- 6. Patent Medicine Prices Review Board - Annual Report 2009, page 38
- 7. Patent Medicine Prices Review Board - Annual Report 2009, page 38

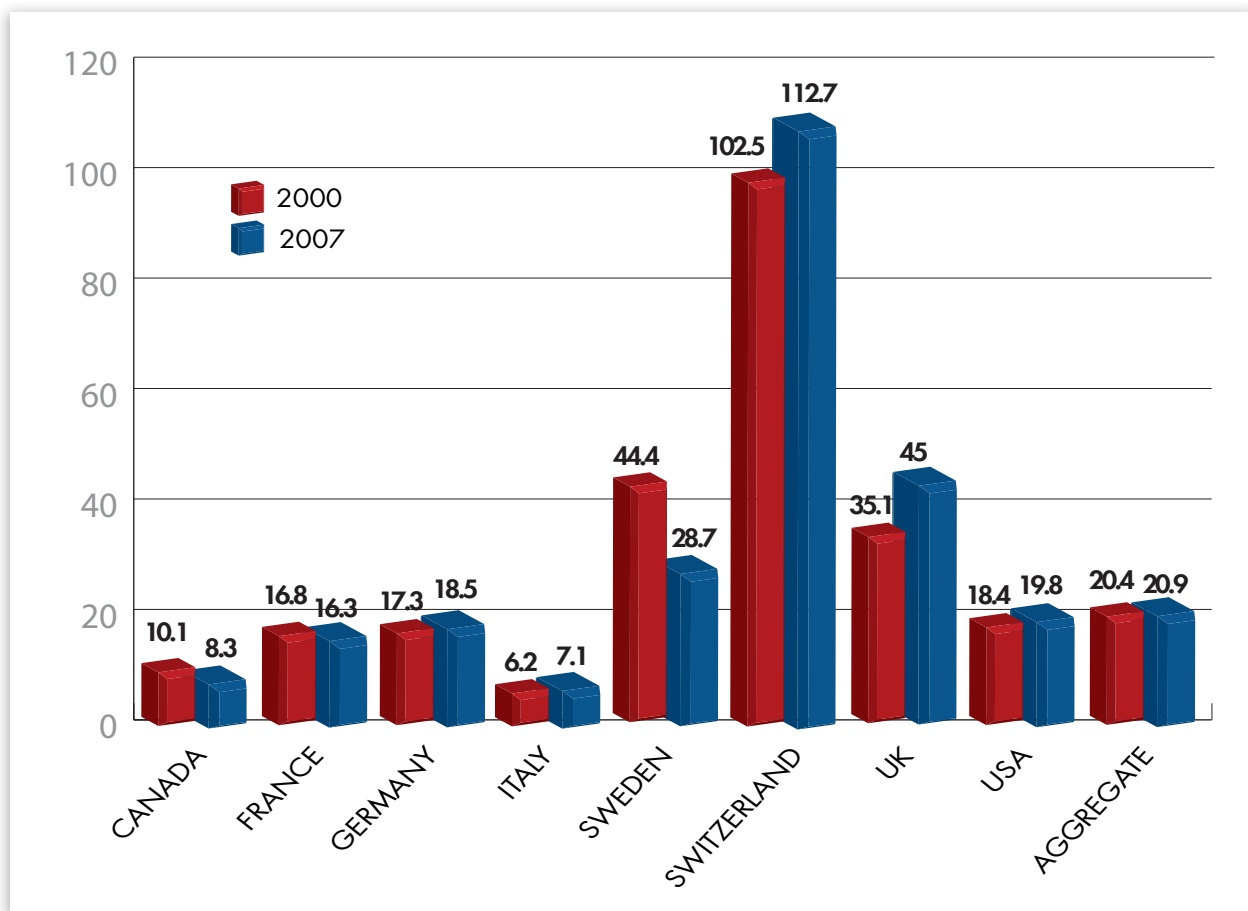


CANADA'S PHARMACEUTICAL R&D-TO-SALES RATIO SECOND WORST OF ALL COUNTRIES

The PMPRB's 2009 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 R&D-to-sales ratio was 10.1%. Only Italy (6.2%) had a lower ratio. 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%).

R&D-TO-DOMESTIC-SALES RATIOS, CANADA AND SEVEN COMPARATOR COUNTRIES, 2000 & 2007 ⁸



In 2007, Canada's R&D-to-sales ratio was second lowest at 8.3%, with Italy (7.1%) at the bottom of the range. Ratios in all other comparator countries remained significantly higher than Canada's. The aggregate ratio for R&D spending and sales for all comparator countries was 20.9%, two and half times Canada's ratio.⁹

FOOTNOTES:

8. Patent Medicine Prices Review Board - Annual Report 2009, page 40

9. Patent Medicine Prices Review Board - Annual Report 2009, page 40



HISTORY OF INCREASED MARKET MONOPOLIES FOR BRAND-NAME DRUG COMPANIES

1987 – BILL C-22

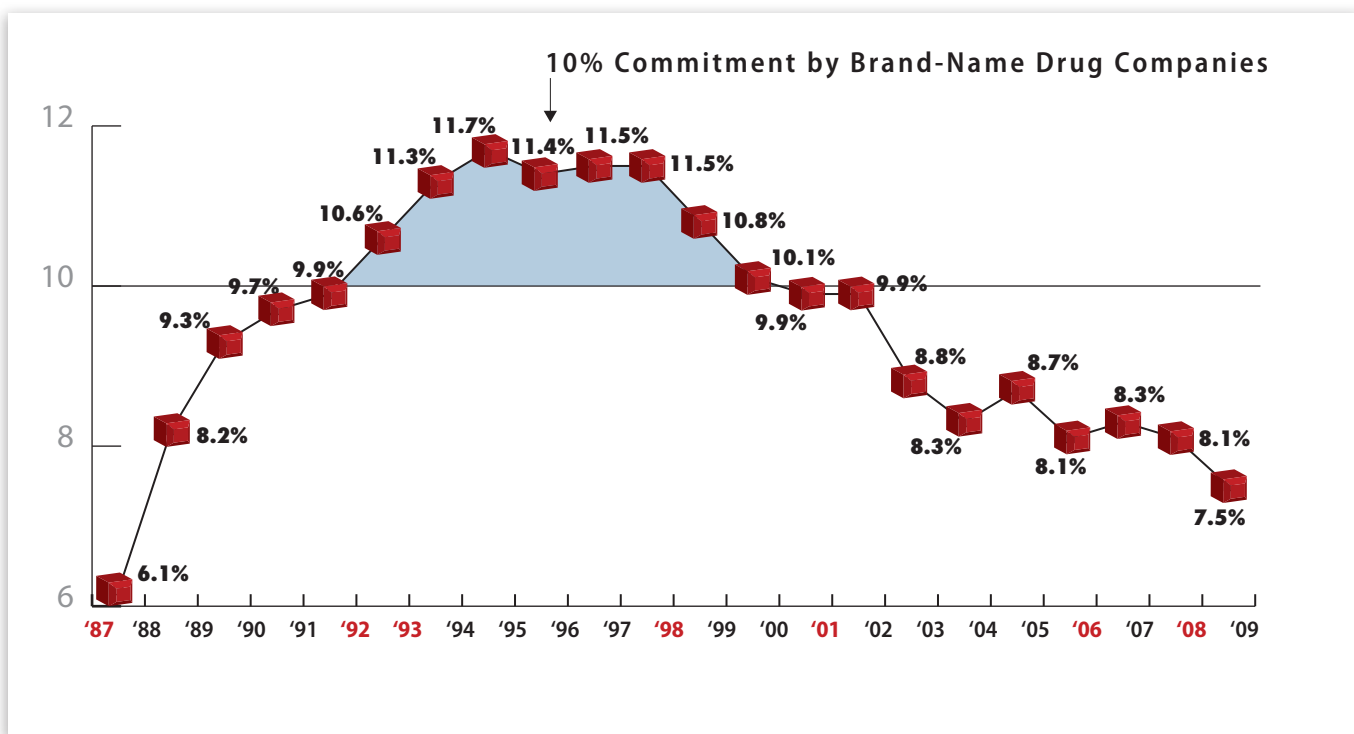
Significant changes are made to the Patent-Act in favour of the brand-name pharmaceutical industry, including an extension of patent terms for new drug products to 20 years from 17 years and limitations on the compulsory licensing regime for pharmaceutical patents. The Patented Medicine Prices Review 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 drug 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 drug companies to prolong their market monopolies – a practice known as “evergreening.”



1987	1992	1993	1998	2001	2006	2008
BILL C-22	BILL C-91	PM (NOC) REGS	Amendments to PM (NOC) regs	BILL S-17	Data exclusivity (8.5 yrs)	Amendments to PM (NOC) regs

1994 – DATA EXCLUSIVITY

Changes to the **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 PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS

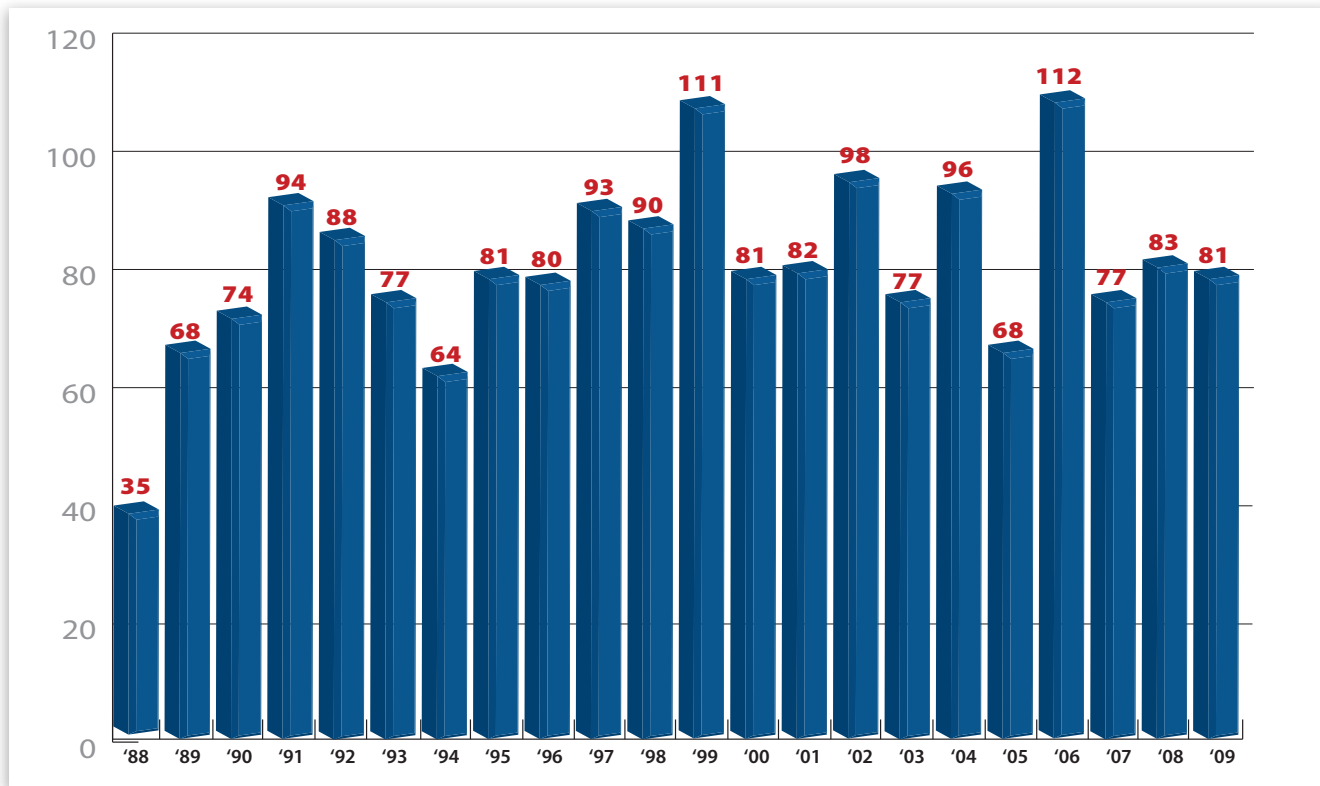
After 13 years of evergreening tactics by brand-name drug companies to unfairly extend market monopolies, amendments are introduced to limit the practice of evergreening. Unnecessary trade-offs were granted to the brand-name pharmaceutical industry, including an extension of Data Exclusivity to 8.5 years (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.

MOST “NEW” DRUGS NOT TRULY INNOVATIVE

The PMPRB reports that there were 81 new patented drug products, or DINs (Drug Identification Numbers), for human use reported as sold in 2009. Some are one or more strengths of new active substances (NAS) and others are new presentations of existing medicines.¹⁰



FOOTNOTES:

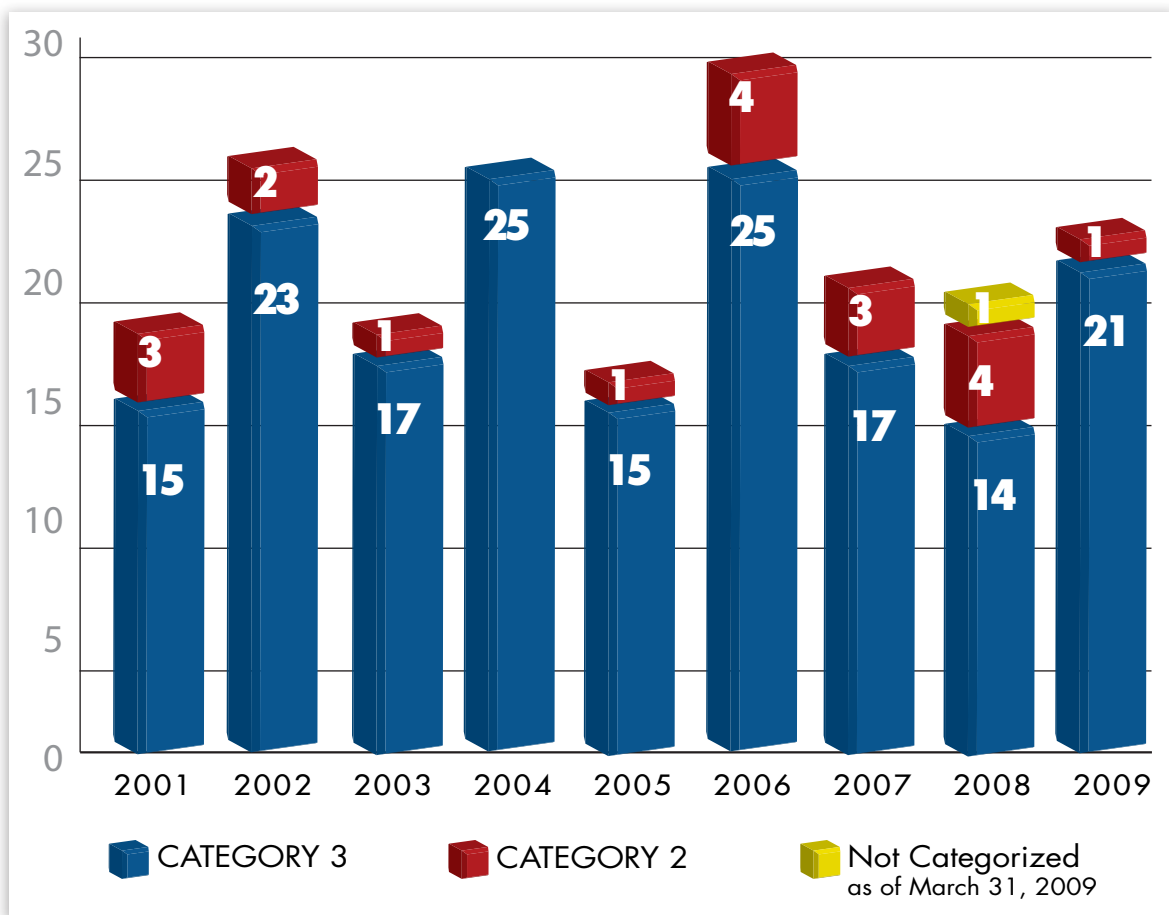
10. Patent Medicine Prices Review Board - Annual Report 2009, page 8



MOST "NEW" DRUGS NOT TRULY INNOVATIVE

The PMPRB's annual report states that a new active substance (NAS) may involve more than one DIN if it is sold in more than one strength or dosage form. In 2009, there were 22 new active substances marketed as 30 DINs.¹¹ Of these, only 1 was in Category 2, which the PMPRB defines as "one that provides a breakthrough or substantial improvement".¹² The vast majority, 21, were in Category 3, which the PMPRB states "provide moderate, little or no therapeutic advantage over comparable medicines."¹³

NEW ACTIVE SUBSTANCES BY THERAPEUTIC CATEGORY, 2001 TO 2009



FOOTNOTES:

11. Patent Medicine Prices Review Board - Annual Report 2009, page 9

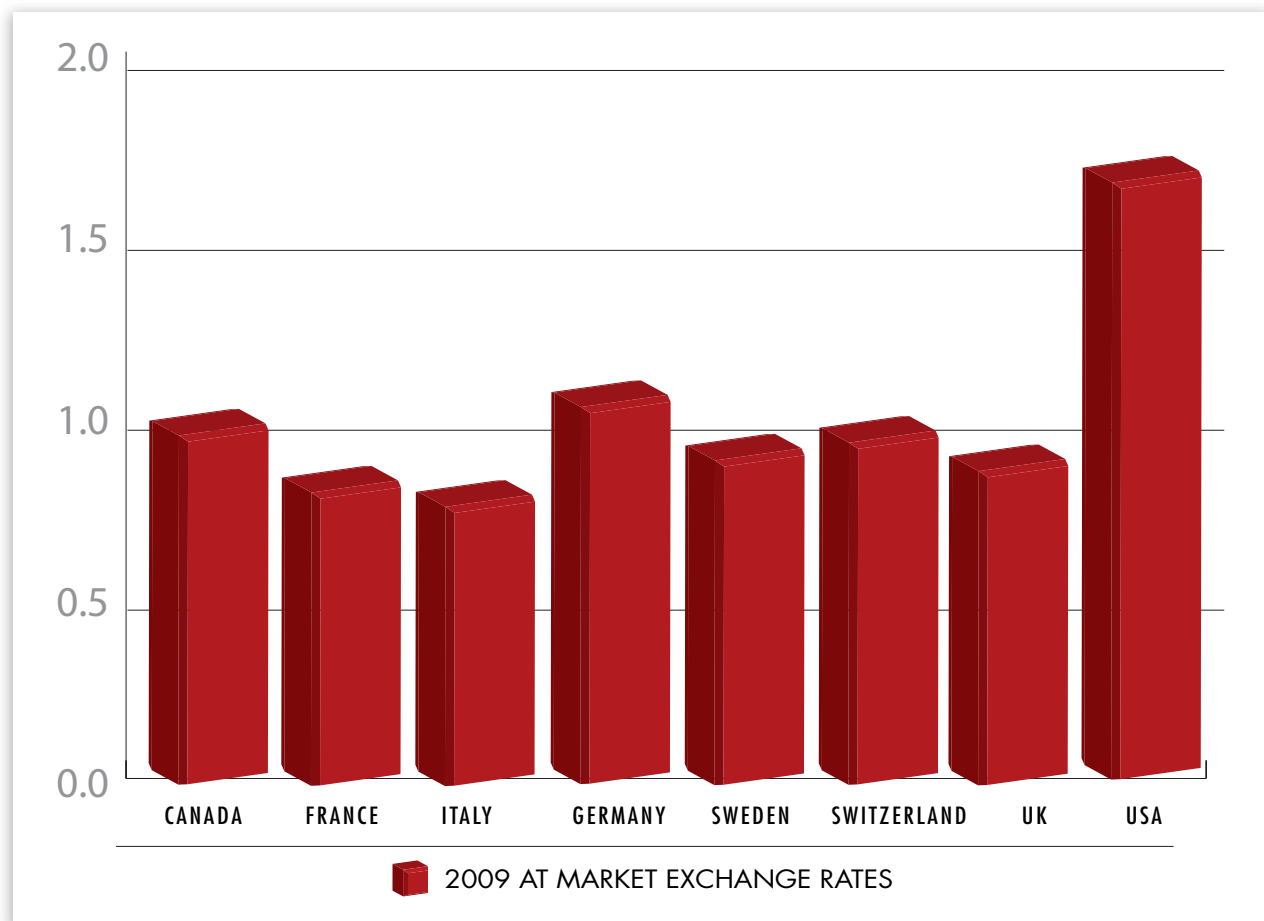
12. Patent Medicine Prices Review Board - Compendium of Guidelines, Policies and Procedures, 2008, page 21

13. Patent Medicine Prices Review Board - Compendium of Guidelines, Policies and Procedures, 2008, page 21



PRICES OF PATENTED DRUGS IN CANADA THIRD HIGHEST IN THE WORLD

AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS FOR PATENTED MEDICINES, 2009 ¹⁴



The PMPRB reports that In 2009 Canadian prices were, on average, significantly higher than prices in Italy and France, much below prices in the United States, but within a margin of plus or minus 10% of prices in Germany, Sweden, Switzerland and the United Kingdom.¹⁵

FOOTNOTES:

14. Patent Medicine Prices Review Board - Annual Report 2009, page 29

15. Patent Medicine Prices Review Board - Annual Report 2009, page 29

