



“ **THE REAL STORY...** ”

*Research & Development Spending by Brand-Name
Drug Companies in Canada: 1988 - 2015*

**R&D-To-Sales Ratio
Less Than Half
of 10% Commitment**

Brand-Name Drug Company R&D Spending Ratio Less Than Half the Annual Threshold Committed to in 1988

Brand companies continue to break 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 by 1996.¹

The 2015 Annual Report of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are again breaking their promise to Canadians. For the 13th consecutive year, members of **Innovative Medicines Canada** (formerly Canada's Research-Based Pharmaceutical Companies—Rx&D) did not meet their R&D-to-sales ratio commitment and spent only 4.9% of their annual revenue on research and development.²

Innovative Medicines Canada members invested less than half of the 10% level the industry promised when the Government of Canada passed Bill C-22 in 1988.

Total R&D Expenditures and R&D-To-Sales Ratios by Innovative Medicines Canada Patentees - 1988 To 2015³

	R&D Expenditures Innovative Medicines Canada Patentees (\$M)	Percent Change From Previous Year	Sales Revenues Innovative Medicines Canada Patentees (\$M)	R&D-To-Sales Ratio: Innovative Medicines Canada Patentees (%)
2015	767.4	7.8	15,565.1	4.9
2014	711.7	2.0	14,861.1	4.8
2013	697.5	-15.4	13,614.8	5.1
2012	824.1	-8.6	13,162.8	6.3
2011	901.2	-9.9	13,446.1	6.7
2010	1,000.2	-11.7	12,149.0	8.2
2009	1,132.9	-3.4	13,780.0	8.2
2008	1,172.2	-1.0	13,178.2	8.9
2007	1,184.4	24.8	13,359.8	8.9
2006	949.0	-8.8	11,131.2	8.5
2005	1,040.1	3.9	11,821.4	8.8
2004	1,000.8	0.8	11,819.0	8.5
2003	992.9	-3.6	10,865.7	9.1
2002	1,029.6	10.1	10,323.8	10.0
2001	935.2	14.7	8,835.4	10.6
2000	815.5	4.0	7,728.8	10.6
1999	784.3	9.9	6,923.4	11.3
1998	713.7	8.6	5,640.2	12.7
1997	657.4	10.3	5,098.2	12.9
1996	595.8	6.5	4,859.5	12.3
1995	559.5	9.8	4,468.8	12.5
1994	509.5	10.4	4,407.2	11.6
1993	461.4	24.0	4,321.4	10.7
1992	372.1	9.0	3,778.4	9.8
1991	341.4	24.7	3,546.9	9.6
1990	273.8	25.8	2,967.9	9.2
1989	217.6	34.7	2,685.5	8.1
1988	161.5	-	2,502.3	6.5

NOTES:

1. Patented Medicine Prices Review Board – Annual Report 2015, page 46

2. Ibid, page 48

3. Ibid, page 48

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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 injunction 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.”

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.

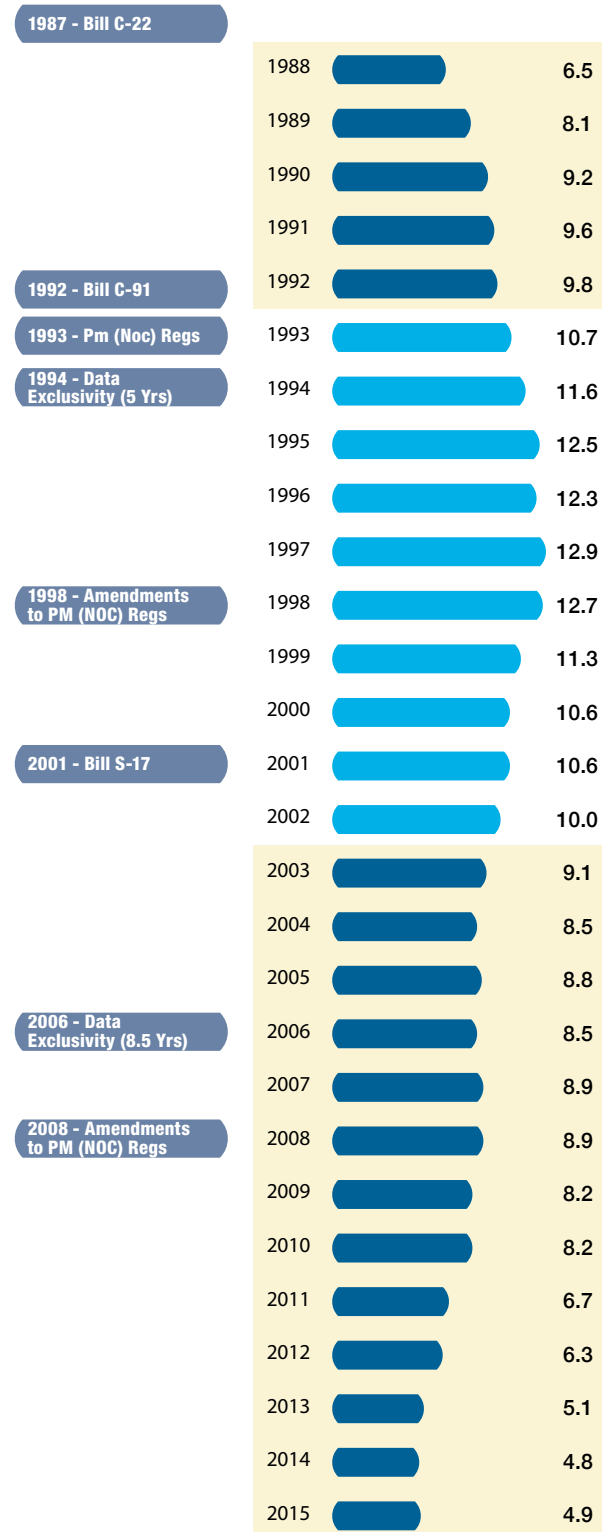
1998: Amendments to Patented Medicines (Notice of Compliance) Regulations — Amendments are made to the PM(NOC) Regulations but these fail to curb evergreening practices.

2001: BILL S-17 — Extends the terms of certain “Old Act” patents under **Bill C-22** to 20 years from the date of 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 of the **PM(NOC) Regulations**, which provides for damages to generic manufacturers when they are wrongly delayed in coming to market.

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.

Legislative History and Innovative Medicines Canada Member Company’s R&D Investment History...



For 18 out of the last 27 years Innovative Medicines Canada Member Companies did not meet their 10% R&D investment commitment.

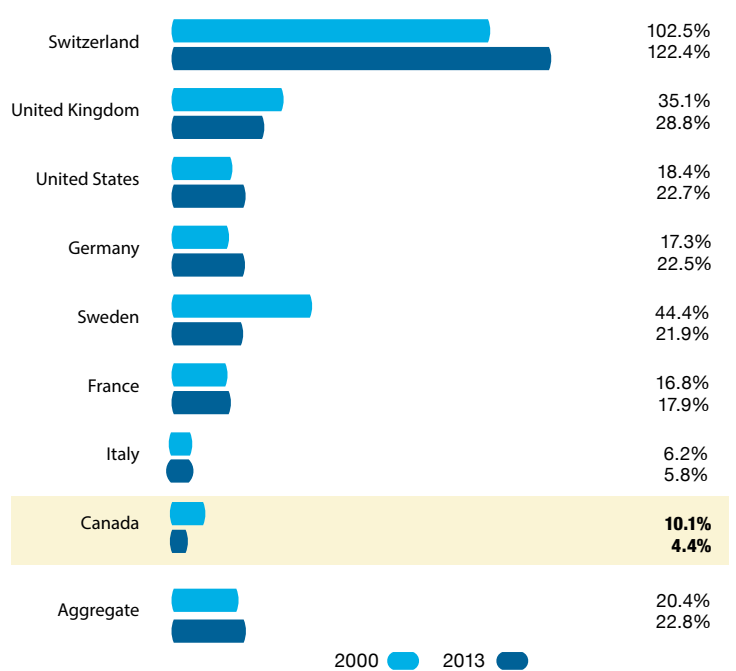
Canada is at the bottom in R&D-to-Domestic-Sales Ratio of Seven Comparator Countries

The PMPRB's **2015 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.

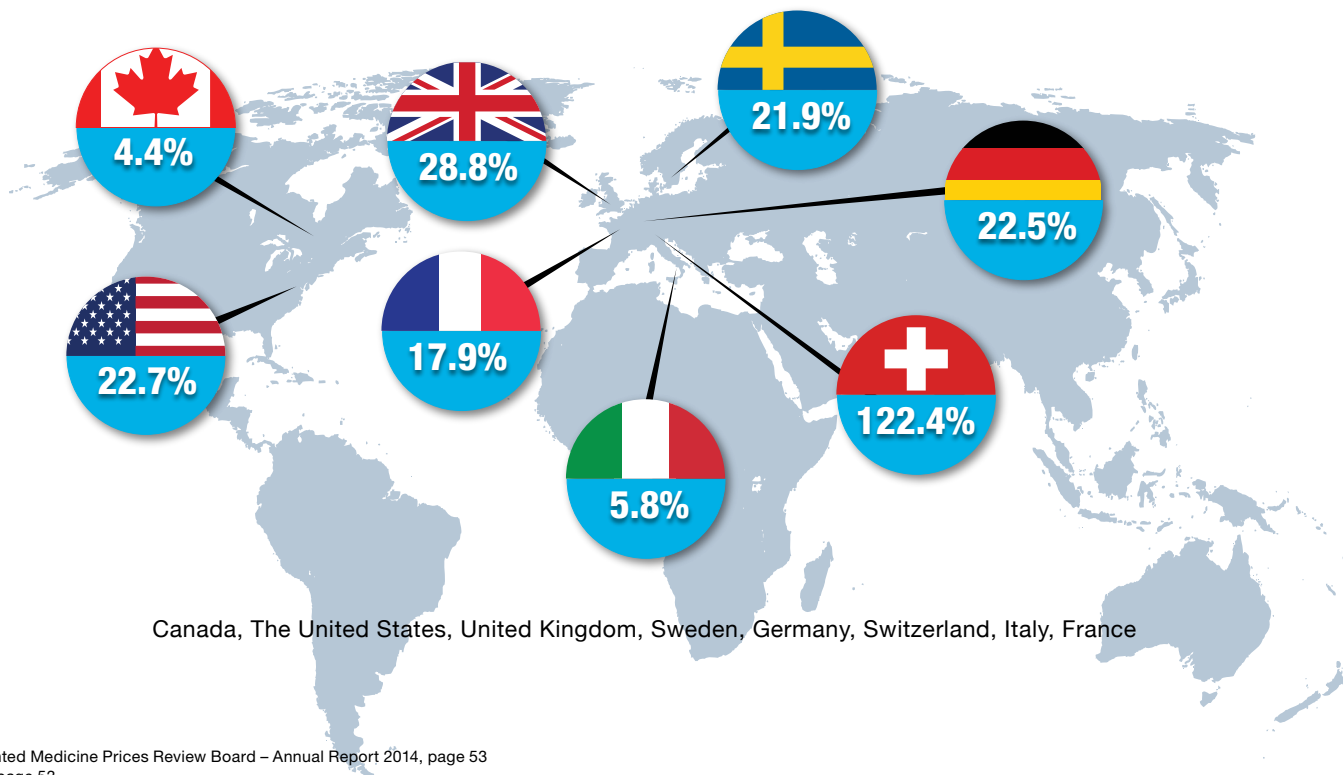
In 2000, the Canadian R&D-to-sales ratio was 10.1%. Only Italy (6.2%) had a lower ratio. Switzerland had the highest ratio at 102.5%.⁴

In 2013, Canada remained at the bottom of the range at 4.4%, with Italy second lowest at 5.8%. Ratios in all other comparator countries remained well above Canada's ratio. The aggregate ratio for R&D spending to domestic sales for all comparator countries was 22.8% – **a full five times the value obtained for Canada.**⁵

R&D-to-Domestic-Sales Ratios, Canada and Seven Comparator Countries - 2000 and 2013 ⁶



R&D-TO-DOMESTIC-SALES RATIOS - CANADA TO 7 COMPARATOR COUNTRIES - 2013 ⁷



Canada, The United States, United Kingdom, Sweden, Germany, Switzerland, Italy, France

NOTES:

4. Patented Medicine Prices Review Board – Annual Report 2014, page 53

5. Ibid, page 53

6. Ibid, page 53

7. Ibid, page 53