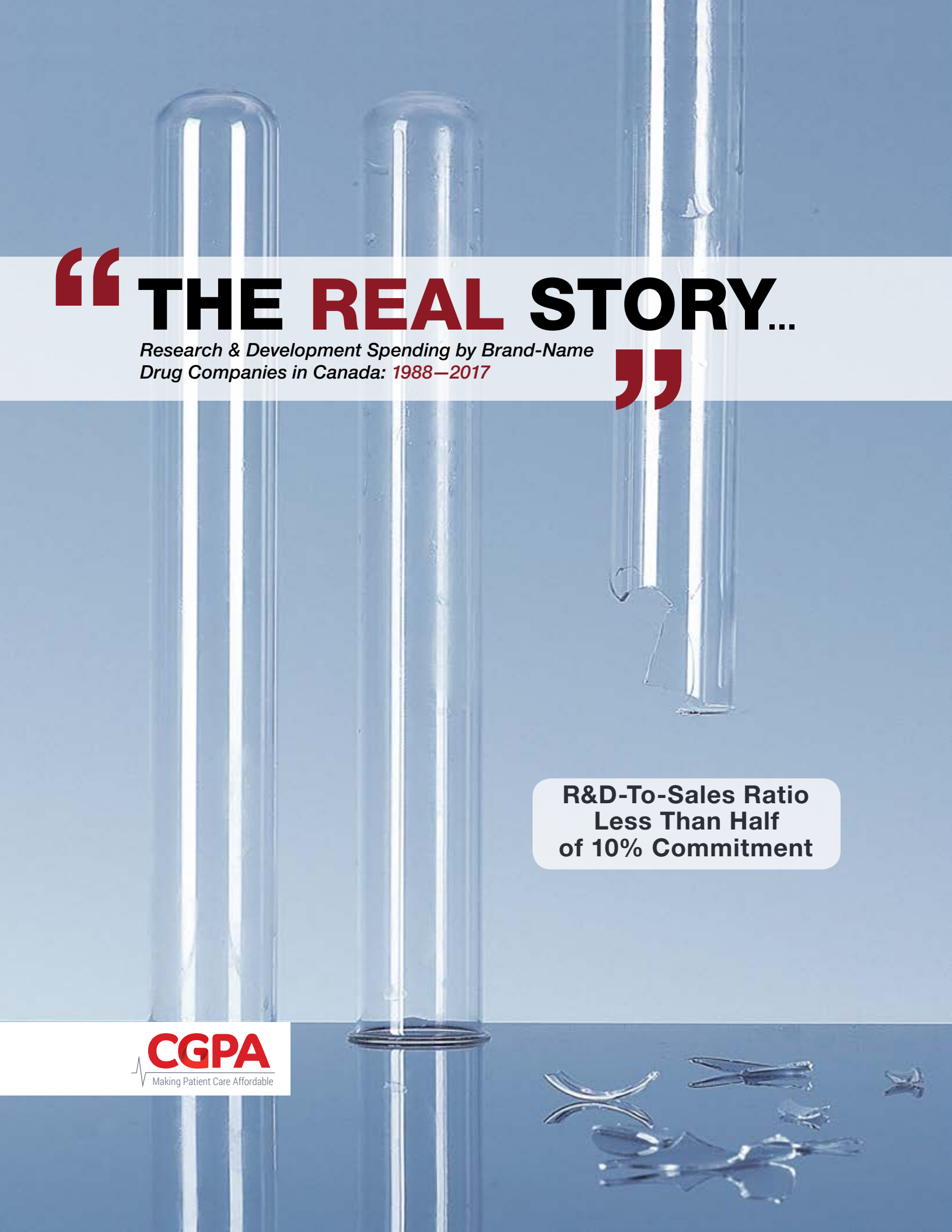


# “THE REAL STORY...”

*Research & Development Spending by Brand-Name Drug Companies in Canada: 1988—2017*

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

CGPA
Making Patient Care Affordable

# 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 2017 Annual Report* of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are again breaking their promise to Canadians. For the 15th 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 4.6% of their annual revenue on research and development in 2017.[2] This is a decrease from 4.9% in 2016.

**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 2017[3]

| | 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 (%) |
|---|---|---|---|---|
| **2017** | **755.8** | **-1.8** | **16,349.8** | **4.6** |
| 2016 | 769.9 | 0.3 | 15,599.9 | **4.9** |
| 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 2017, page 55
2. Ibid, page 56
3. Ibid, page 56

# HISTORY OF INCREASED MARKET MONOPOLIES FOR BRAND-NAME DRUG COMPANIES

## Legislative History ...

**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***.

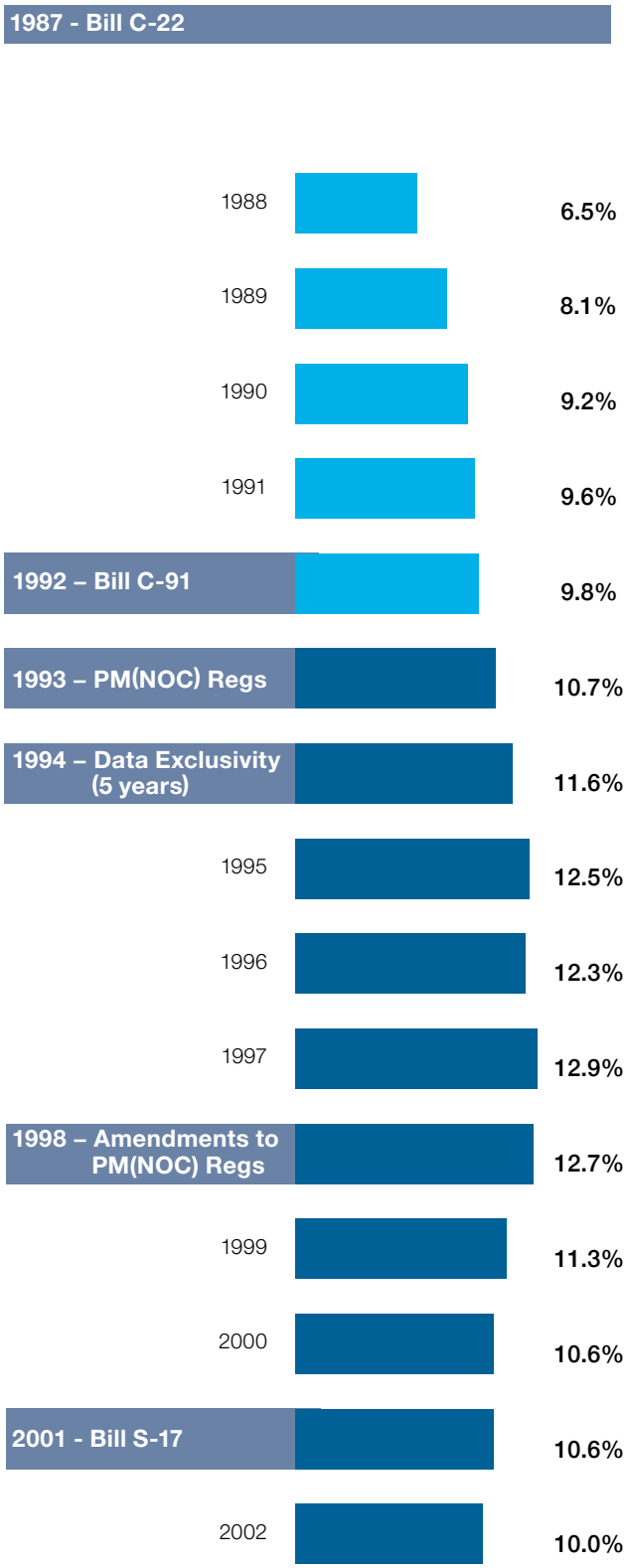
**1993: Introduction of *Patented Medicines (Notice of Compliance) Regulations*** — These regulations include a 30-month automatic injunction provision (later reduced to 24 months) that provided brand-name drug companies with the means to delay the market entry of generic competition without the burden 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 introduce 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.

## Innovative Medicines Canada Member Company's R&D Investment History ...



# HISTORY OF INCREASED MARKET MONOPOLIES FOR BRAND-NAME DRUG COMPANIES

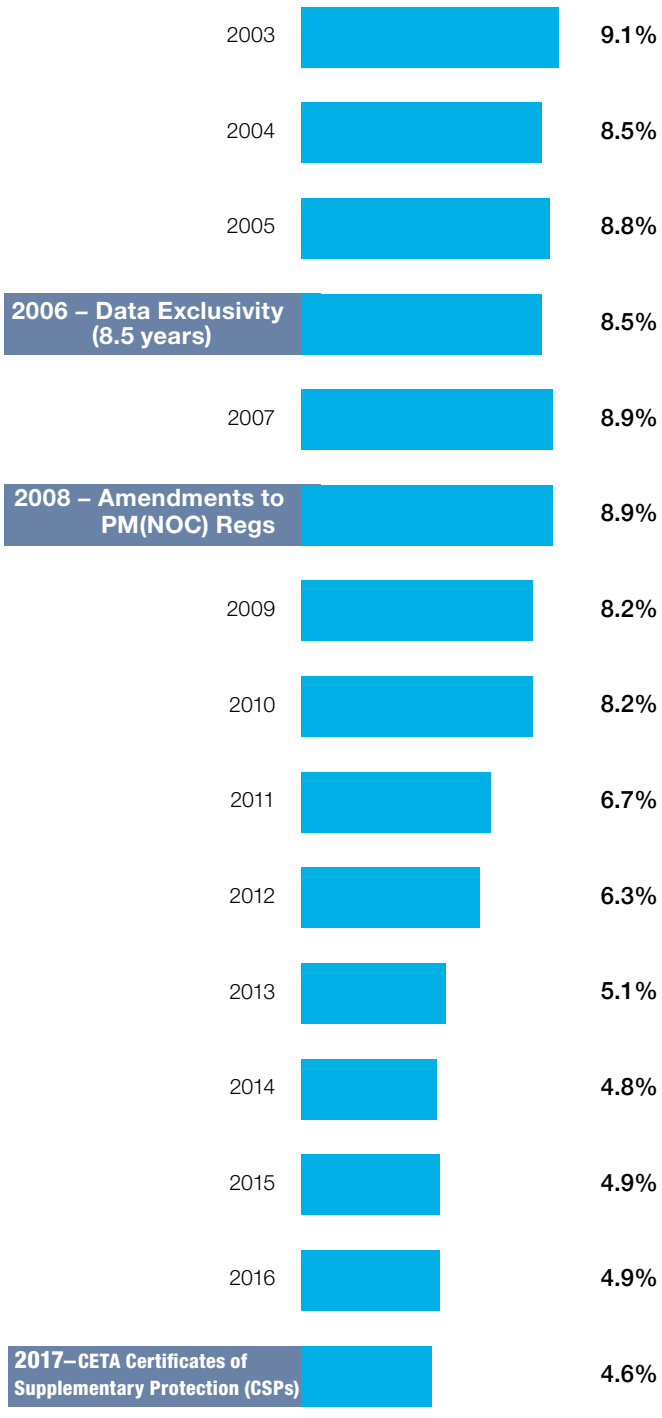
## Legislative History ...

**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.

**2017: Introduction of *Certificates of Supplementary Protection (CSPs)*** — A new "patent term extension" system is implemented through amendments to the Patent Act and the new Certificate of Supplementary Protection Regulations as a result of concessions made by Canada in the **Comprehensive Economic and Trade Agreement** (CETA) with the European Union. Most new brand-name pharmaceutical products approved are eligible for an additional two years of market monopoly. The Parliamentary Budget Officer has conservatively estimated that this delay in competition from generic and biosimilar medicines will cost Canadians more than $500 million annually.

## Innovative Medicines Canada Member Company's R&D Investment History ...




**For 20 of the last 30 years Innovative Medicines Canada Member Companies did not meet their 10% R&D investment commitment.**

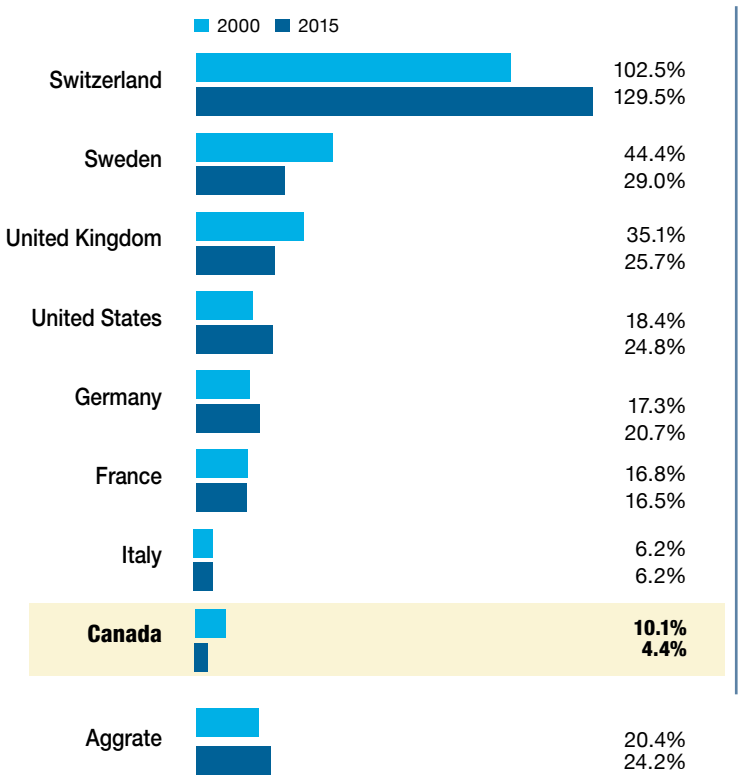
## CANADA IS AT THE BOTTOM IN R&D-TO-DOMESTIC-SALES RATIO COMPARED TO PMPRB7

The PMPRB's 2017 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.

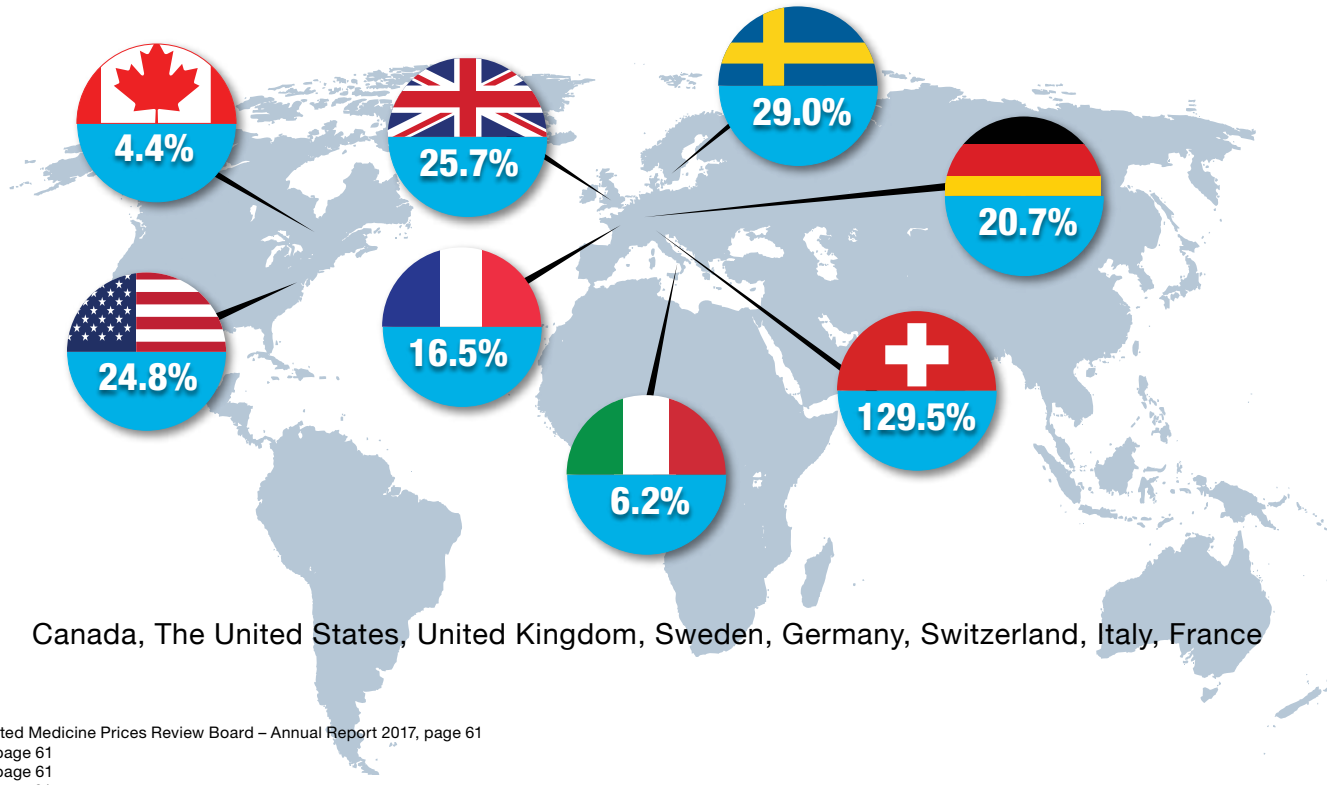
In 2000, the Canadian R&D-to-sales ratio was 10.1%. Only Italy (6.2%) had a lower ratio. Switzerland had the highest ratio at 102.5%.[4]

**In 2015, Canada remained at the bottom of the range at 4.4%**, with Italy second lowest at 6.2%. Ratios in all other comparator countries remained well above Canada's ratio. The international aggregate ratio for R&D spending to domestic sales was 24.2% – **more than five times the value obtained for Canada.**[5]

**R&D-to-Domestic-Sales Ratios, Canada PMPRB7 - 2000 and 2015[6]**




**R&D-TO-DOMESTIC-SALES RATIO - CANADA TO PMPRB7 COUNTRIES - 2015 [7]**




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

NOTES:
4. Patented Medicine Prices Review Board – Annual Report 2017, page 61
5. Ibid, page 61
6. Ibid, page 61
7. Ibid, page 61