

# THE REAL STORY BEHIND R&D SPENDING



## BY **BRAND-NAME** DRUG COMPANIES IN CANADA

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION - 2011

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## BRAND 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 by 1996.<sup>1</sup>

The 2010 Annual Report of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are continuing to break their promise to Canadians. For the tenth consecutive year, pharmaceutical patentees' domestic R&D-to-sales ratio has fallen below the level the industry promised when the Government of Canada passed Bill C-22.

Pharmaceutical patentees spent only 6.9% of their Canadian revenues on research and development in 2010, below the 10% threshold the industry committed to in 1987.<sup>2</sup> This is the lowest ratio reported by pharmaceutical patentees since 1988.

### TOTAL R&D EXPENDITURES AND R&D-TO-SALES RATIOS - 1988 TO 2010<sup>3</sup>

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 (%)
<b>2010</b>	<b>82</b>	<b>1,178.2</b>	<b>-7.4</b>	<b>17,000.0</b>	<b>-0.3</b>	<b>6.9</b>
2009	81	1,272.0	<b>-2.9</b>	17,051.9	4.5	<b>7.5</b>
2008	82	1,310.7	<b>-1.1</b>	16,316.7	2.0	<b>8.1</b>
2007	82	1,325.0	<b>9.5</b>	15,991.0	7.3	<b>8.3</b>
2006	72	1,210.0	<b>-9.1</b>	14,902.0	4.7	<b>8.1</b>
2005	80	1,234.3	<b>5.5</b>	14,231.3	0.5	<b>8.7</b>
2004	84	1,170.0	<b>-2.0</b>	14,168.3	4.0	<b>8.3</b>
2003	83	1,194.3	<b>-0.4</b>	13,631.1	12.8	<b>8.8</b>
2002	79	1,198.7	<b>13.0</b>	12,081.2	12.5	<b>9.9</b>
2001	74	1,060.1	<b>12.6</b>	10,732.1	15.3	<b>9.9</b>
2000	79	941.8	<b>5.3</b>	9,309.6	12.0	<b>10.1</b>
1999	78	894.6	<b>12.0</b>	8,315.5	19.2	<b>10.8</b>
1998	74	798.9	<b>10.2</b>	6,975.2	10.9	<b>11.5</b>
1997	75	725.1	<b>9.0</b>	6,288.4	7.4	<b>11.5</b>
1996	72	665.3	<b>6.4</b>	5,857.4	9.9	<b>11.4</b>
1995	71	625.5	<b>11.5</b>	5,330.2	7.5	<b>11.7</b>
1994	73	561.1	<b>11.4</b>	4,957.4	4.4	<b>11.3</b>
1993	70	503.5	<b>22.1</b>	4,747.6	14.0	<b>10.6</b>
1992	71	412.4	<b>9.6</b>	4,164.4	6.9	<b>9.9</b>
1991	65	376.4	<b>23.2</b>	3,894.8	18.1	<b>9.7</b>
1990	65	305.5	<b>24.8</b>	3,298.8	11.0	<b>9.3</b>
1989	66	244.8	<b>47.4</b>	2,973.0	9.4	<b>8.2</b>
1988	66	165.7	-	2,718.0	-	<b>6.1</b>

NOTES:

1. Patented Medicine Prices Review Board – Annual Report 2010, page 33

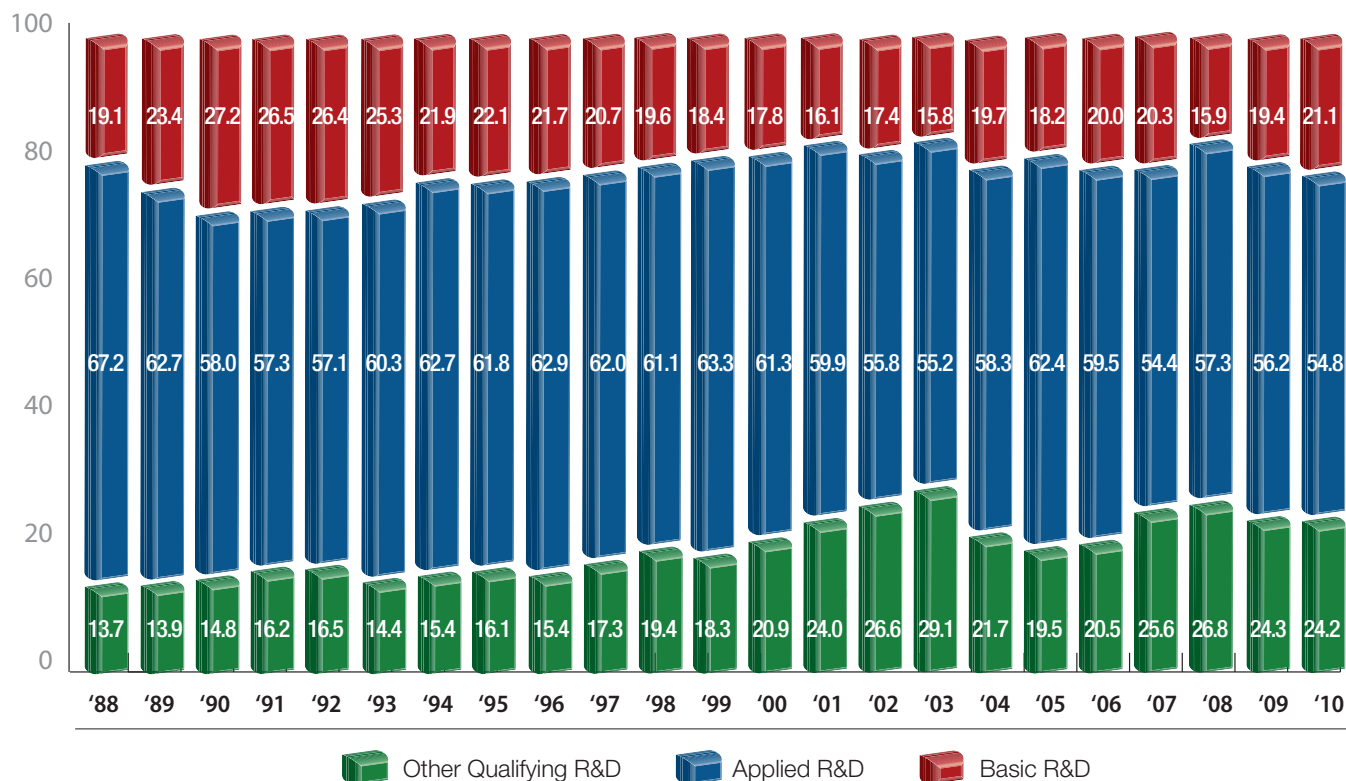
2. Patented Medicine Prices Review Board – Annual Report 2010, page 32

3. Patented Medicine Prices Review Board – Annual Report 2010, page 32

## ONLY 1.4% OF CANADIAN SALES REVENUE SPENT ON BASIC RESEARCH

Patentees reported spending \$235.9 million on basic research in 2010, representing 21.1% of current R&D expenditure. This represents just 1.4% of their Canadian sales revenue.<sup>4</sup>

### R&D EXPENDITURES BY TYPE OF RESEARCH FROM 1998 TO 2010<sup>5</sup>



## CLINICAL TRIALS ACCOUNT FOR 75.8% 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 \$613.4 million on applied research, representing 54.6% of current R&D expenditure. Clinical trials accounted for 75.8% of applied research expenditures.<sup>6</sup>

Other qualifying research, which includes drug regulation submissions, bioavailability studies and Phase IV clinical trials, accounted for the remaining 24.2% of the research expenditure in 2010.<sup>7</sup>

#### NOTES:

4 Patented Medicine Prices Review Board – Annual Report 2010, page 34

5 Patented Medicine Prices Review Board – Annual Report 2010, page 34

6 Patented Medicine Prices Review Board – Annual Report 2010, page 34

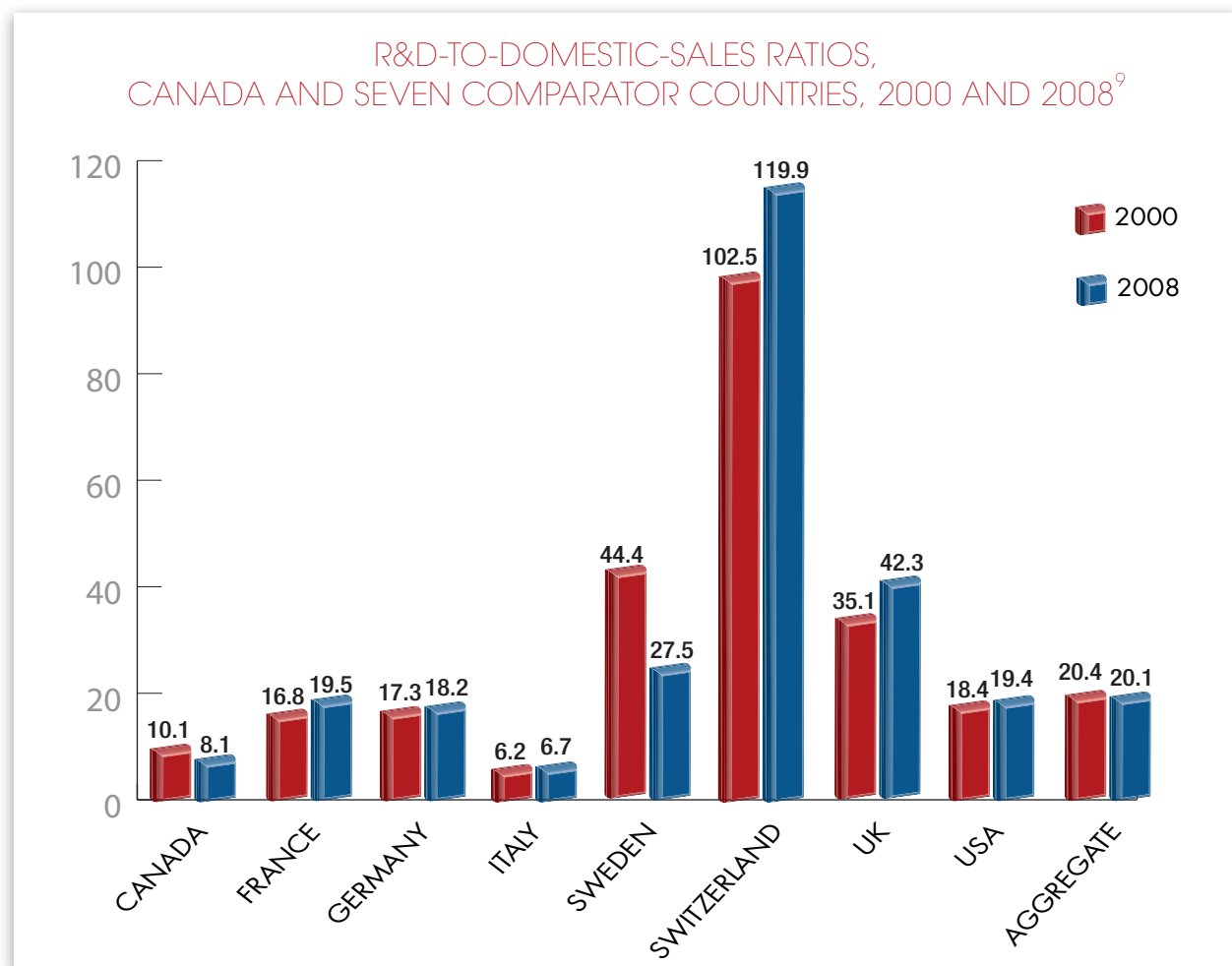
7 Patented Medicine Prices Review Board – Annual Report 2010, page 34

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

The PMPRB's 2010 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%).

In 2008, Canada was second lowest at 8.1% with Italy (6.7%) at the bottom of the range. Ratios in all other comparator countries remained significantly higher than that of Canada. The aggregate ratio for R&D spending and sales for all comparators countries was 20.1%, two and a half times Canada's ratio.<sup>8</sup>



NOTES:

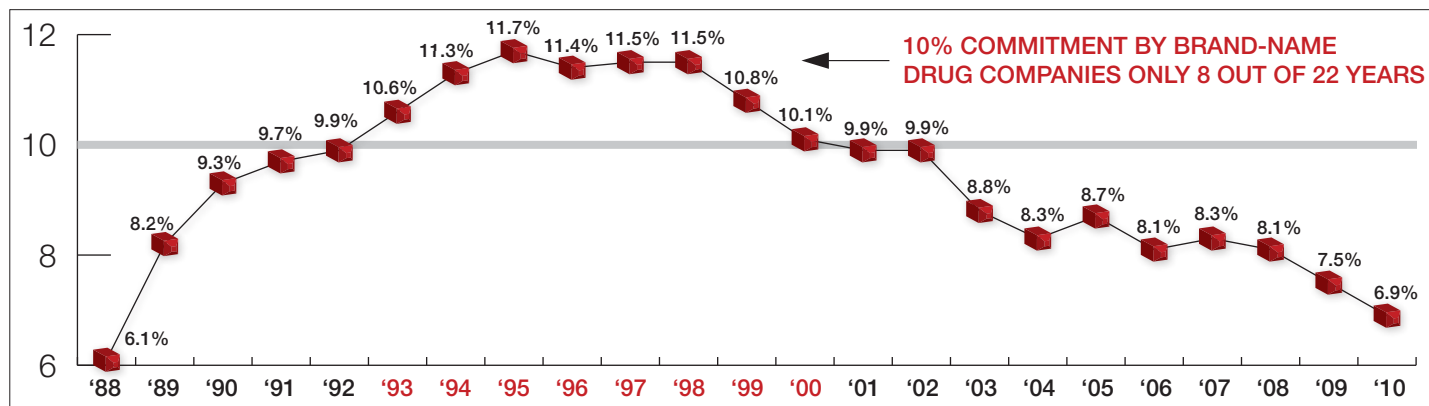
8 Patented Medicine Prices Review Board – Annual Report 2010, page 36

9 Patented Medicine Prices Review Board – Annual Report 2010, page 36

## 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.



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

### 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.”

### 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.