

# **The Real Story Behind R&D Spending by Brand-Name Drug Companies in Canada**

**Canadian Generic Pharmaceutical Association**

**2009**

**GENERIC DRUGS.**



**SAME QUALITY. LOWER PRICE.**

**Canadian Generic Pharmaceutical Association**

4120 Yonge Street, Suite 409, Toronto ON M2P 2B8 Tel: (416) 223-2333 [www.canadiangenerics.ca](http://www.canadiangenerics.ca)

## **Table of Contents**

	<b>Page</b>
Brand drug companies breaking R&D spending commitment to Canadians.....	1
Total R&D Expenditures and R&D-to-Sales Ratios, 1988-2008.....	1
Only 1.2% of sales revenue spent on basic research.....	2
R&D expenditure by Type of Research, 1988-2008.....	2
Clinical trials account for 75% of applied research.....	2
Canada's pharmaceutical R&D-to-sales ratio second worst of all countries.....	3
R&D-to-domestic-sales ratios, Canada and 7 comparator countries, ..... 2000 and 2006	3
History of Increased Market Monopolies for Brand-Name Drug Companies.....	4
Most "New" Drugs Not Truly Innovative.....	5
Prices of Patented Drugs in Canada Third Highest in the World.....	7
Average Foreign-to-Canadian Price Ratios for Patented Medicines, 2008.....	7
Pharmaceutical Patentees Overcharged \$43 Million in 2008/2009.....	8
Summary of Voluntary Compliance Undertakings and Board Orders..... —Total Excess Revenues	8

### **GENERIC DRUGS.**



**SAME QUALITY. LOWER PRICE.**

### **Canadian Generic Pharmaceutical Association**

4120 Yonge Street, Suite 409  
Toronto, Ontario M2P 2B8  
Tel: (416) 223-2333  
Fax: (416) 223-2425  
Email: [info@canadiangenerics.ca](mailto:info@canadiangenerics.ca)  
Website: [www.canadiangenerics.ca](http://www.canadiangenerics.ca)

## The Real Story Behind R&D Spending by Brand-Name Drug Companies in Canada

### 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 their annual domestic research and development (R&D) expenditure to 10% of Canadian sales revenue.<sup>1</sup>

The 2008 Annual Report of the Patented Medicine Prices Review Board (PMPRB) shows brand-name companies are continuing to break their promise to Canadians. For the eighth consecutive year, pharmaceutical patentees' 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 8.1% of their Canadian revenues on research and development in 2008, below the 10% threshold the industry committed to in 1987.<sup>2</sup> While the 2008 R&D-to-sales ratio of 8.1% is identical to the ratio reported in 2006, these are the lowest ratios reported by pharmaceutical patentees in the past 20 years.

### Total R&D Expenditures and R&D-to-Sales Ratios, 1988-2008<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 (%)
2008	82	1,310.7	-1.1	16,316.7	2.0	8.1
2007	82	1,325.0	9.5	15,991.0	7.3	8.3
2006	72	1,210.0	-1.9	14,902.0	4.7	8.1
2005	80	1,234.3	5.5	14,231.3	0.5	8.7
2004	84	1,170.0	-2.0	14,168.3	4.0	8.3
2003	83	1,194.3	-0.4	13,631.1	12.8	8.8
2002	79	1,198.7	13.0	12,081.2	12.5	9.9
2001	74	1,060.1	12.6	10,732.1	15.3	9.9
2000	79	941.8	5.3	9,309.6	12.0	10.1
1999	78	894.6	12.0	8,315.5	19.2	10.8
1998	74	798.9	10.2	6,975.2	10.9	11.5
1997	75	725.1	9.0	6,288.4	7.4	11.5
1996	72	665.3	6.4	5,857.4	9.9	11.4
1995	71	625.5	11.5	5,330.2	7.5	11.7
1994	73	561.1	11.4	4,957.4	4.4	11.3
1993	70	503.5	22.1	4,747.6	14.0	10.6
1992	71	412.4	9.6	4,164.4	6.9	9.9
1991	65	376.4	23.2	3,894.8	18.1	9.7
1990	65	305.5	24.8	3,298.8	11.0	9.3
1989	66	244.8	47.4	2,973.0	9.4	8.2
1988	66	165.7	-	2,718.0	-	6.1

<sup>1</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 42

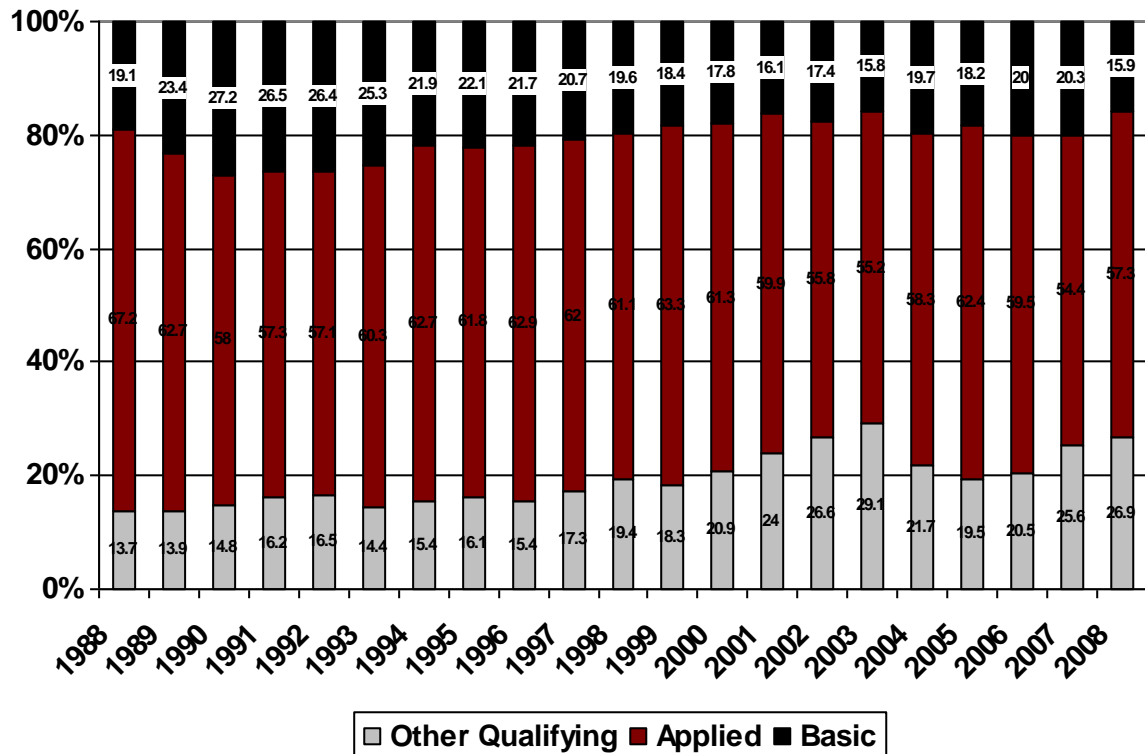
<sup>2</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 41

<sup>3</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 41

### Only 1.2% of Canadian sales revenue spent on basic research

Patentees reported spending \$200.2 million on basic research in 2008, representing 15.9% of current R&D expenditure and a decrease of 22.7% over the previous year. This represents just 1.2% of their Canadian sales revenue.<sup>4</sup>

### R&D Expenditure by Type of Research, 1988-2008<sup>5</sup>



### Clinical trials account for 75% 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 \$723.2 million on applied research, representing 57.3% of domestic R&D expenditure. Clinical trials accounted for 74.6% of the applied research expenditure.<sup>6</sup>

Other qualifying research, which includes drug regulation submissions, bioavailability studies and Phase IV clinical trials, accounted for the remaining 26.9% of the research expenditure in 2008.<sup>7</sup>

<sup>4</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 43

<sup>5</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 43

<sup>6</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 43

<sup>7</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 43

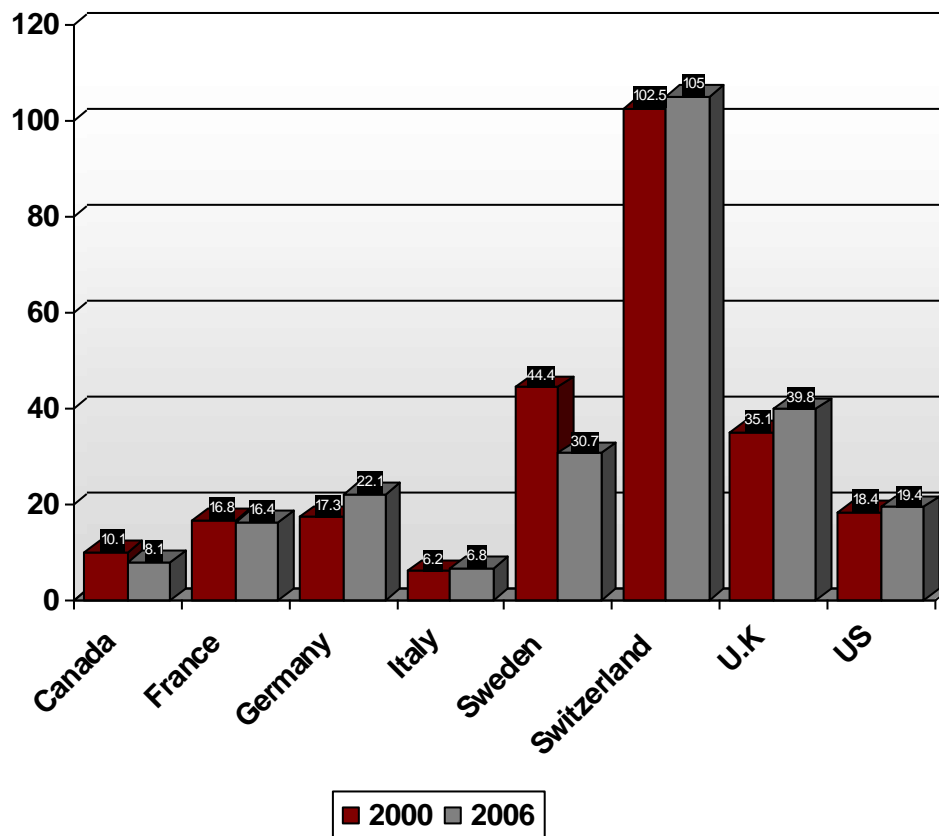
### Canada's pharmaceutical R&D-to-sales ratio second worst of all countries

The PMPRB's 2008 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 investment-to-sales ratios for 2006. Italy (6.8%) remained at the bottom of the range, with Canada second lowest at 8.1%. Ratios in all other comparator countries remained well above Canada's ratio.<sup>8</sup>

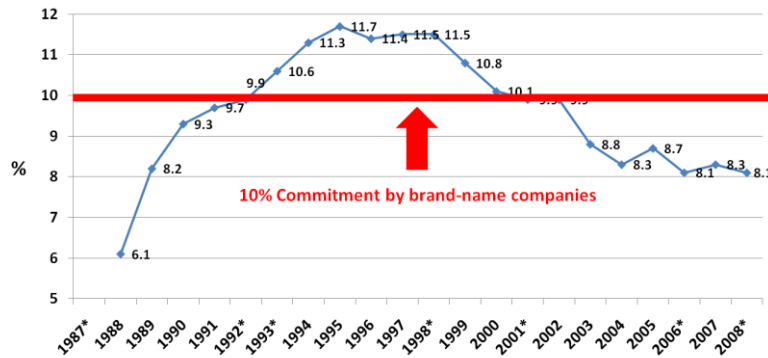
**R&D-to-domestic-sales ratios, Canada and 7 Comparator countries, 2000 and 2006<sup>9</sup>**



<sup>8</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 45

<sup>9</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 45

## History of Increased Market Monopolies for 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 Years)	Amendments to PM(NOC) Regs

### 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

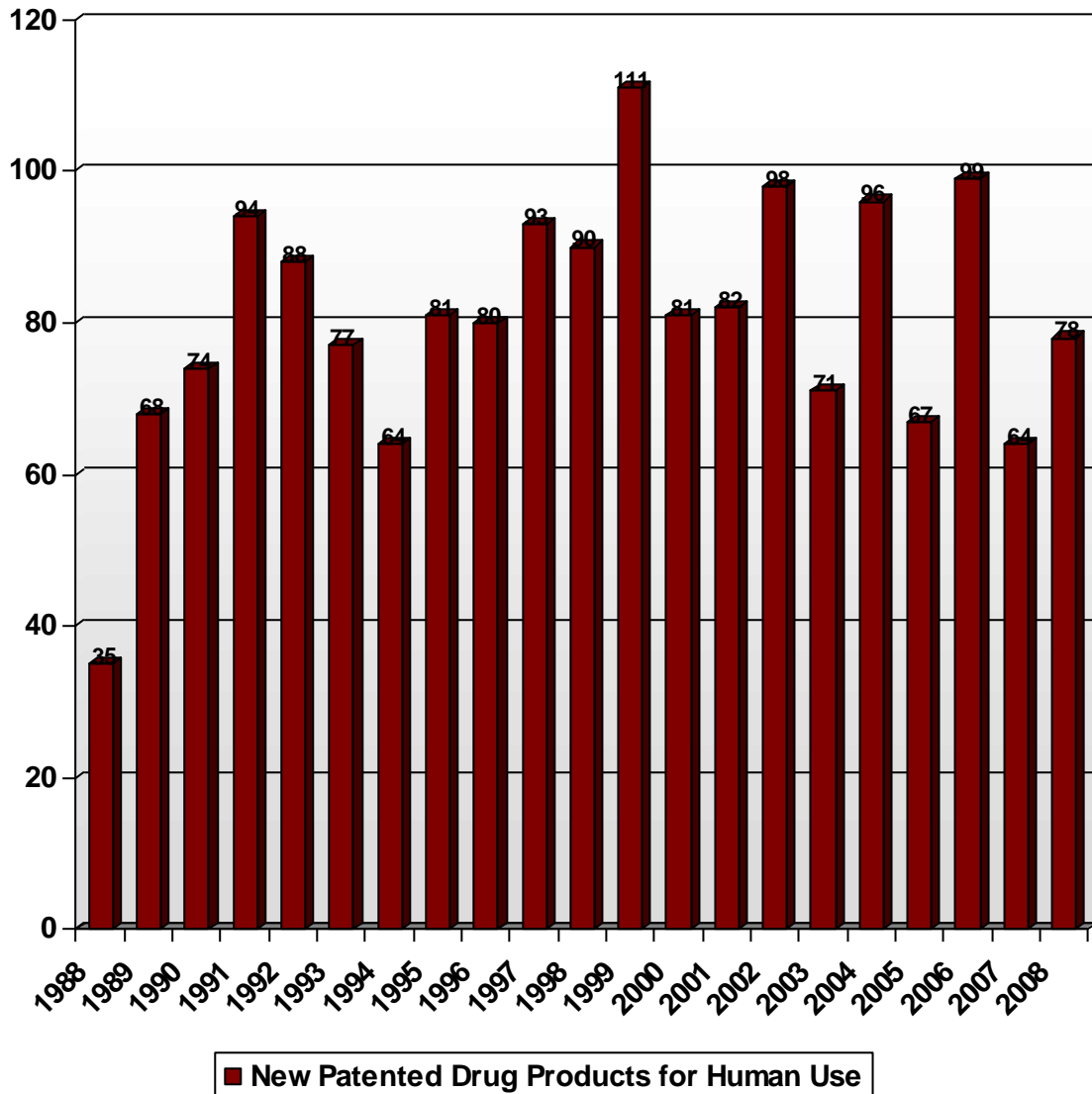
After 13 years of evergreening tactics by brand-name drug companies to unfairly extend market monopolies, amendments are introduced to limit the practice of evergreening. Unnecessary trade-offs were granted to the brand-name pharmaceutical industry, including an extension of Data Exclusivity to 8.5 years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

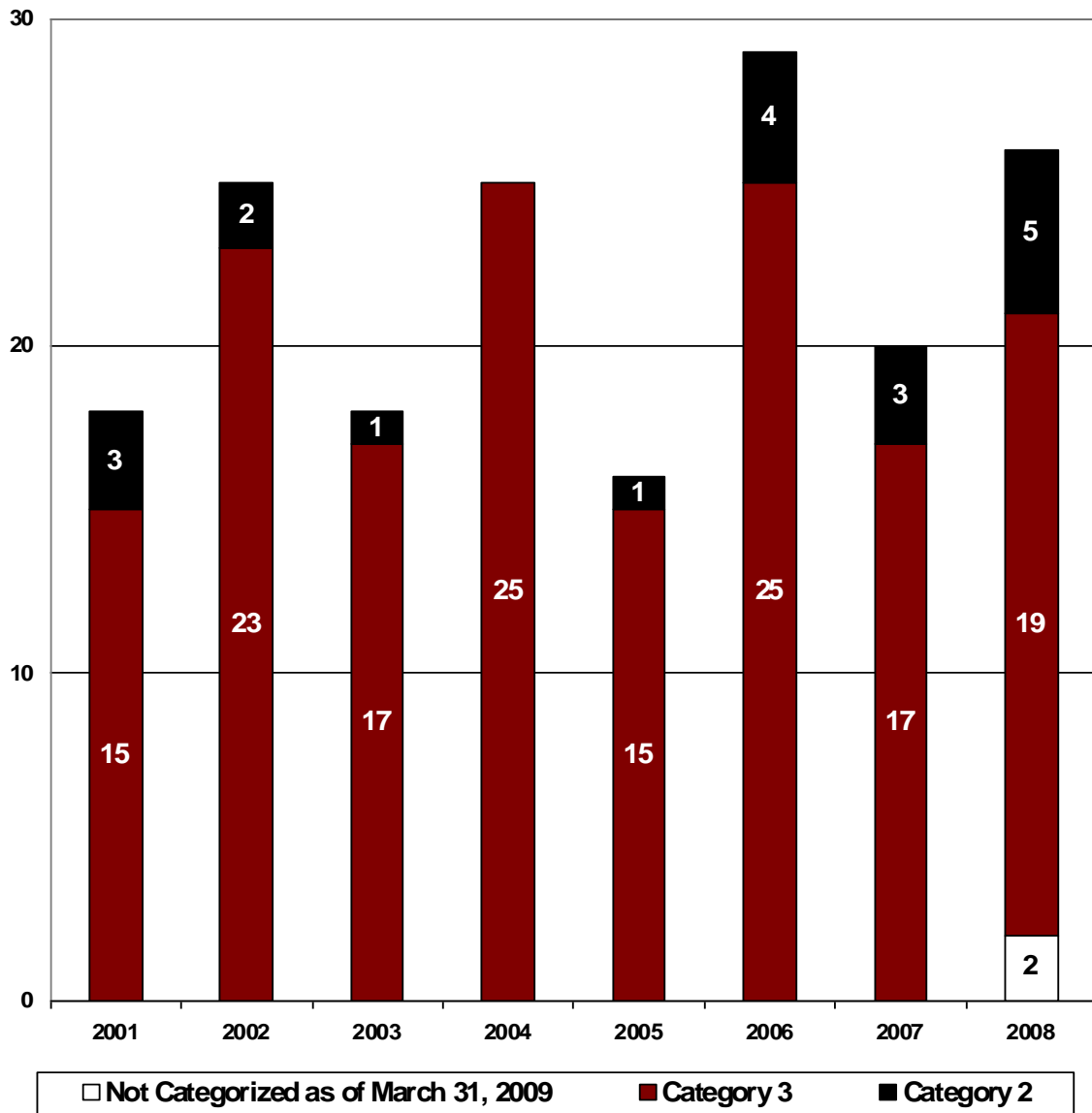
### Most “New” Drugs Not Truly Innovative

There were 78 new patented drug products, or DINs (Drug Identification Numbers), for human use introduced in 2008. Some are one or more strengths of new active substances (NAS) and others are new presentations of existing medicines.<sup>10</sup>



<sup>10</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 10

In 2008, there were 19 new active substances marketed as 26 DINs.<sup>11</sup> Of these, only 5 were in Category 2, which the PMPRB defines as “one that provides a breakthrough or substantial improvement”.<sup>12</sup> The majority, 19, were in Category 3, which the PMPRB states “provide moderate, little or no therapeutic advantage over comparable medicines.”<sup>13</sup> The remaining 2 new active substances were not categorized as of March 31, 2009.



<sup>11</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 10

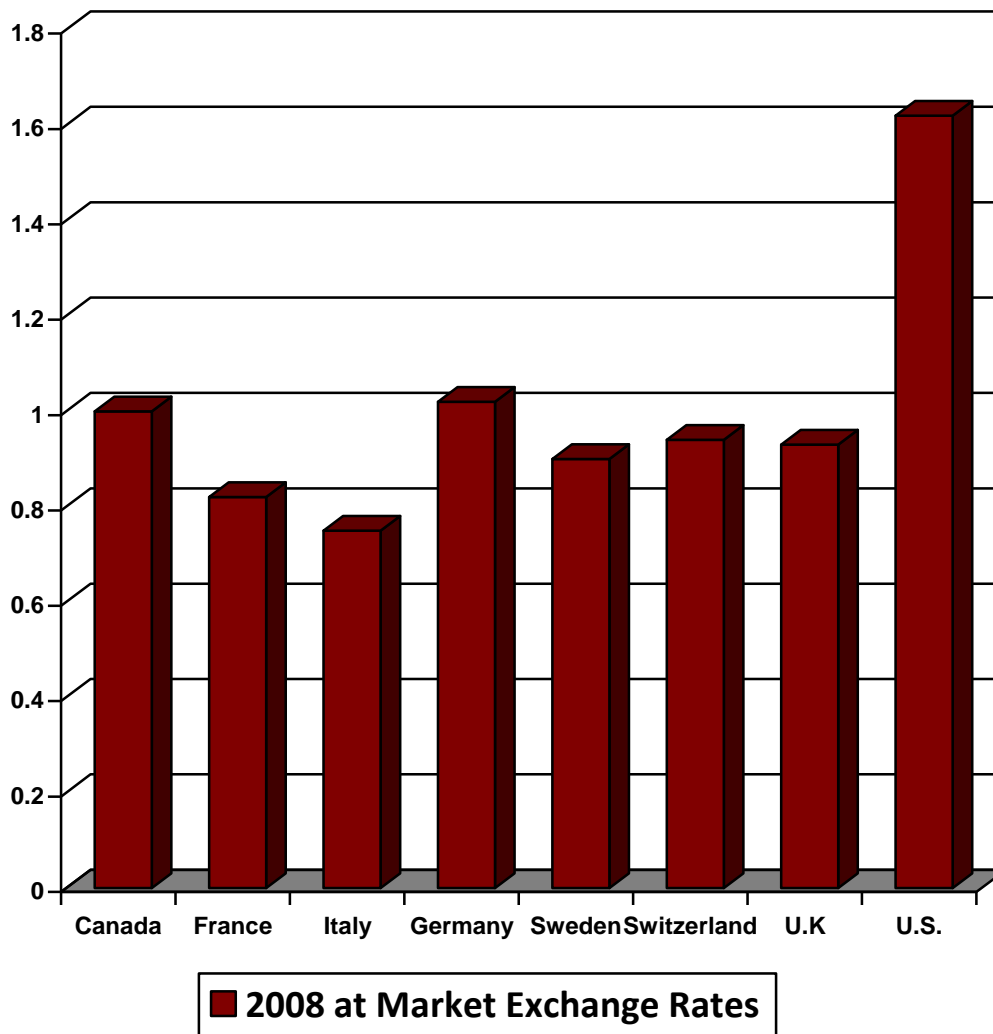
<sup>12</sup> Patented Medicine Prices Review Board – Compendium of Guidelines, Policies and Procedures, 2008, page 21

<sup>13</sup> Patented Medicine Prices Review Board – Compendium of Guidelines, Policies and Procedures, 2008, page 21

## Prices of Patented Drugs in Canada Third Highest in the World

Prices of patented medicines in Canada are the third highest in the world and virtually the same as the second highest priced jurisdiction, Germany.

### Average Foreign-to-Canadian Price Ratios for Patented Medicines, 2008<sup>14</sup>



Prices in Italy and France were, on average, substantially less than Canadian prices. As in previous years, 2008 U.S. prices were substantially higher than in Canada and all other comparator countries.<sup>15</sup>

<sup>14</sup>Patented Medicine Prices Review Board – Annual Report 2008, page 32

<sup>15</sup>Patented Medicine Prices Review Board – Annual Report 2008, page 32

## Pharmaceutical Patentees Overcharged \$43 Million in 2008/2009

The PMPRB reports that between February 28, 2008 and April 24, 2009 patentees earned “Excess Revenues” of approximately \$43 million for 11 drug products.<sup>16</sup> The Board reported that companies involved have either paid the federal government a fee or reimbursed customers.

### Summary of Voluntary Compliance Undertakings and Board Orders – Total Excess Revenues<sup>17</sup>

Date of Approval	Medicine	Patentee	Excess Revenues	Excess Revenues Offset by Payments to the Government of Canada
April 24, 2009	Concerta	Janssen-Ortho Inc.	\$1,464,441.58	\$1,464,441.58
April 23, 2009	Eligard	sanofi-aventis Canada Inc.	\$13,127,953.14	\$13,127,953.14
March 4, 2009	Suprax	sanofi-aventis Canada Inc.	\$97,900.30	\$97,900.30
February 23, 2009	Vepesid	Bristol-Myers Squibb Canada Co.	\$53,161.48	Customers
February 19, 2009	Strattera	Eli Lilly Canada Inc.	\$15,326,066.49	\$15,326,066.49
September 29, 2008	Adderall XR – ORDER	Shire Canada Inc.	\$5,622,863.63	\$5,622,863.63
June 25, 2008	AndroGel	Solvay Pharma Inc.	\$3,327,180.61	\$3,327,180.61
			\$399,206.25	\$399,206.25
			\$16,573.84	\$16,573.84
June 11, 2008	Copaxone – ORDER	Teva Neuroscience	\$2,417,223.29	\$2,417,223.29
May 20, 2008	Denavir	Barrier Therapeutics Canada Inc.	\$61,021.80	\$61,021.80
March 4, 2008	Lantus	sanofi-aventis Canada Inc.	\$694,239.50	\$694,239.50
February 28, 2008	Vaniqa	Barrier Therapeutics Canada Inc.	\$70,860.59	\$70,860.59
<b>Totals</b>			<b>\$42,678,692.50</b>	<b>\$42,625,531.02</b>

<sup>16</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 54

<sup>17</sup> Patented Medicine Prices Review Board – Annual Report 2008, page 54