

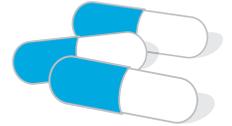


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Drug Price Controls and Pharmaceutical Innovation



The perception that major pharmaceutical firms "gouge" the ill is widespread and gaining ground. The mandate of the Patented Medicine Prices Review Board (PMPRB), a quasi-judicial Canadian federal body, is closely linked to this belief and aims to prevent companies from charging excessive prices. Since 1987, the federal government has controlled the prices of patented drugs by means of the PMPRB starting from their launch, with increases tied to the consumer price index.

Drug costs have undeniably risen more quickly than other health care costs. The share of drugs in overall Canadian health care spending went from 10.8% in 1988 to 15.7% in 2001.¹ However, the higher drug expenses facing Canada's health care systems are not due to price increases imposed by multinational pharmaceutical firms. It is true that newer drugs cost more than old ones. But doctors choose these drugs for their improved therapeutic effects, avoiding or reducing hospital care and its associated costs.² Various other factors explain the growth in drug spending. These include more frequent use of drugs (more prescriptions per patient per year and the fact that a growing number of people are under medication) as well as higher mark-ups at the wholesale and retail levels,³ which have nothing to do with the prices charged by manufacturers.

But if "control of drug prices at the factory level does not necessarily mean control of total expenditures," by the PMPRB's own admission,⁴ it seems even less justified if its indirect economic consequences are taken into account. Artificially low price levels for patented drugs and the resulting distortions in the price structure hinder the introduction of new drugs. Price controls also create a business climate that reduces the incentives for pharmaceutical companies to invest in maintaining and

developing their R&D activities in Canada, leading ultimately to losses for the entire economy.

Lower prices than in other countries

Since 1995, Canadian prices of patented drugs have been 5% to 12% lower than median international prices among the seven comparator countries: Italy, France, Sweden, Germany, the United Kingdom, Switzerland and the United States. The only exception was 2002, when Canadian prices came in close to median international prices (Figure 1). That year, for example, they were 67% less than American prices, 5.4% less than Swiss prices and 4.3% less than British prices.

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In addition, because of controls, the *real* prices of patented drugs in Canada - with inflation taken into account - have actually been falling for several years. Between 1998 and 2002, the nominal prices of patented drugs increased by an annual average of just 0.6%, compared to 1.9% for the prices of all drugs and 2.5% for the consumer price index. This means real prices for patented drugs fell by 1.9%. In 2002, this decrease was even greater, reaching 3.5%.⁵

¹ Data from the Canadian Institute for Health Information; calculations by the author.

² Ministère de la Santé et des Services sociaux du Québec, *L'assurance-médicaments : un acquis social à préserver*, mai 2002.

³ PMPRB, *2002 Annual Report*, 2003, p. 25.

⁴ *Ibid.*, p. 24.

⁵ *Ibid.*, p. 21 ; calculations by the author.



Distorting the price structure

Distortions in the price structure are another perverse effect of price controls. This effect is harder to pinpoint and measure but is nonetheless very real. Price distortions are the direct result of the PMPRB's administrative price-fixing procedures.

First, one of the PMPRB's guidelines stipulates that the cost of therapy using a new drug must not exceed the cost of existing therapy in Canada with older drugs. It is obvious that such reasoning is partial and fails to take account of the advantages that new drugs provide in terms of well-being for patients and a reduction in other expenses for the health care system as a whole. U.S. studies show, for example, that each additional dollar spent on new drugs reduces hospital spending by US \$3.25.⁶

Second, to estimate the price of a new drug, the PMPRB relies on the prices of drugs in the same therapeutic category, whether patented or generic.⁷ However, R&D spending on patented drugs took place 10 or even 15 years earlier (when costs were much lower), while R&D costs for generic drugs are almost nil because they are copies of brand-name drugs whose patents have expired.

It is obvious these price-fixing conditions are broadly unfavourable to new drugs whose R&D costs are incomparably higher. A policy of price controls thus

eliminates any incentives for pharmaceutical firms to lower the prices of drugs *already* on the market, since the PMPRB uses them for comparative purposes. Companies prefer to keep these prices higher so that they can launch new drugs at prices providing for fuller recovery of R&D, launch and marketing costs. This situation also leads generic drug producers to sell their goods at higher prices, explaining in part why some generic drugs are more expensive in Canada than in the United States.⁸

In other words, without price controls, companies could use different marketing strategies depending on product type

and life cycle. For example, a strategy of high prices and limited quantities is normally used early in the cycle for drugs providing major therapeutic progress. A strategy of lower prices and larger quantities follows in the middle and later parts of the cycle, at which time similar products are often launched by competitors. But the PMPRB in effect forces companies to adopt uniform pricing

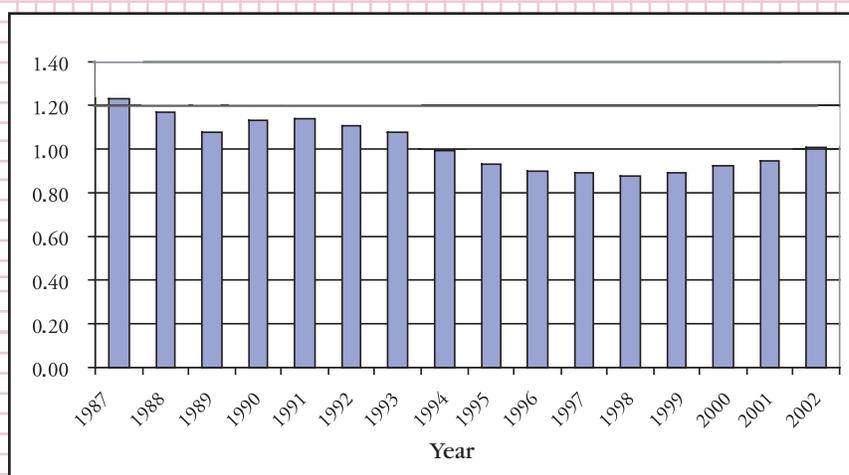
rather than having different marketing strategies. This means Canadians must sometimes pay *higher* prices for older patented drugs than they would without price controls.

Pharmaceutical innovation

The costs - and risks - of discovering and launching a new drug have risen sharply. For example, after adjusting for inflation, the average R&D cost of a new drug went from US\$318 million in 1991 to US\$802 million in 2001

Figure 1

Ratio of average patented drug prices in Canada to median international prices



Source : PMPRB (2003), p. 23.

⁶ Frank R. Lichtenberg, "Do (More and Better) Drugs Keep People Out of Hospitals?", *American Economic Review*, Vol. 86, Issue 2, Papers and Proceedings, May 1996, p. 387.

⁷ J. R. Graham, "Prescription Drug Prices in Canada and the United States - Part 2. Why the Difference?", *Public Policy Sources*, n° 70, 2000, p. 13; available at <http://www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&id=161>. See also PMPRB (2003), p. 10.

⁸ *Ibid.*, p. 14.



(in 2000 dollars).⁹ This includes the costs of discovery as well as pre-clinical and clinical development up to approval by the Food and Drug Administration, which authorizes its sale to the public. The entire R&D process can last 10 to 15 years. As seems logical, these figures also include the cost of having capital tied up during this period. But they do not include the costs of obtaining approval in each country where the drug will be sold nor the marketing and distribution expenses, which can also reach hundreds of millions of dollars. At the same time, R&D productivity is declining because it has become harder to find new molecules; the easier-to-find ones have mostly been discovered already. For each 10,000 molecules at the pre-clinical testing stage, only one will obtain approval and go on commercial sale.¹⁰

Because of this, merely maintaining the current pace of pharmaceutical innovation requires spending a greater share of resources on R&D. In Canada, however, R&D spending in relation to revenues from drug sales is not only lower than in other developed countries¹¹ but has fallen sharply since 1997. In fact, the ratio at companies reporting to the PMPRB went from 11.32% in 1997 to 9.24% in 2002, as Figure 2 shows.

With the costs and risks involved in developing new drugs continuing to rise, price controls make investing in R&D less attractive. They add extra risks and uncertainties, with companies never being sure of the selling prices of their future drugs. Companies may even find themselves having to reimburse sizable sums. For example, Schering Canada Inc. had to reimburse \$7.8 million in 2003 because it charged a price judged as “excessive” for its Remicade drug.

Who would be tempted to invest under these conditions? It is hardly a surprise that investors are pulling out a growing portion of their funds. National subsidiaries of pharmaceutical companies compete for R&D budgets, which are managed centrally, and their allocation is based on revenues and cash flow in each country.¹² Price controls cause a direct reduction in volume. Thus, Canadian subsidiaries are getting a declining number of R&D missions and the proportion of revenues devoted to R&D is falling as a result. At the end of the road, this leads inevitably to slower pharmaceutical innovation. Canada seems to be on the same track as Europe, where there has been a notable drop in pharmaceutical R&D.

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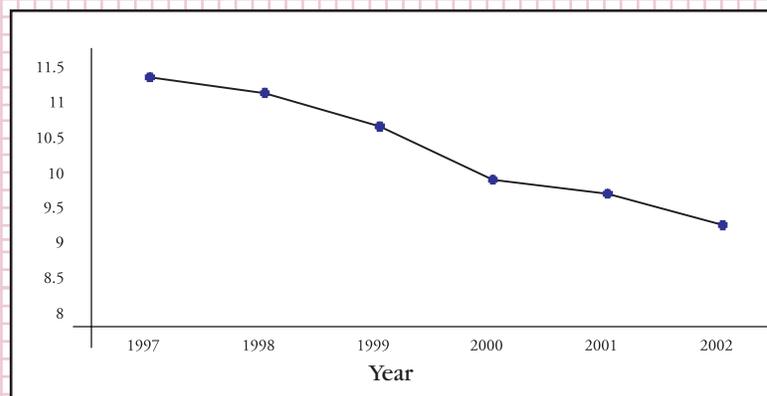
But there are other major costs linked to drug price controls. These include losses of highly skilled jobs, corporate research centres and jobs foregone in the subcontracting of goods and services

and in industries associated with R&D. Another result is lower performance in health care procedures. A recent study provides an example: a full accounting shows that drug price controls saved Germany US \$19 billion in 2002, but the negative consequences cost a total of \$22 billion for an overall loss of \$3 billion.¹³ The same phenomenon poses a

threat to Canada and in particular to Quebec, home to Canada’s largest concentration of pharmaceutical

Figure 2

Ratio of R&D spending to sales revenues at pharmaceutical companies



Source : PMPRB, Annual reports 1998-2003; calculations by the author.

⁹ According to the Tufts Center for the Study of Drug Development. See the article on their site at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6>.

¹⁰ SECOR, *Realizing the Full Benefits of the Canadian Innovation-Based Pharmaceutical Industry*, Montreal, May 2003, p. 39.

¹¹ *Ibid.*, p. 36.

¹² John A. Vernon, “Drug Research and Price Controls”, *Regulation Magazine*, Winter 2002-03, p. 24, available at <http://www.cato.org/pubs/regulation/regv25n4/v25n4-7.pdf>.

¹³ Bain & Co., *Addressing the Innovation Divide*, 2004; available at http://www.bain.com/bainweb/PDFs/cms/Marketing/addressing_innovation_divide.pdf.



R&D, with 42.3% of total spending in 2002.¹⁴ In addition, Quebec is where the ratio of R&D spending to sales revenues is highest.¹⁵ A decline of pharmaceutical research in Canada would hit Quebec hardest.

A price explosion?

Controlling drug prices, like controlling prices of any product or service, undeniably has harmful effects. If there were no controls, would we have to fear a sudden rise in prices toward levels observed in the United States? It is clear that abandoning controls would mean the prices of some innovative drugs would be higher at their launch. This is essential, as the Montmarquette report indicates, “to enable producers to recover their investment.”¹⁶ But general price levels could be expected to remain more or less unchanged, for three reasons.

First, between one-third and one-half of the difference between Canadian and U.S. prices may be due to lawsuits in the United States.¹⁷ A major part of the remaining difference is due to the growing gap in living standards and incomes between Canada and the United States. Companies adjust their prices based on purchasing power in specific markets where they sell their products.



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Second, the provincial governments have considerable negotiating power in obtaining price reductions, equivalent to medium-sized health maintenance organizations (HMOs) in the United States. It is unthinkable for pharmaceutical companies to delay the market launch of new drugs for a year or two while haggling over price. In Canada, nearly half of drug spending is covered by provincial health insurance plans, giving provincial governments control over the introduction of prescription drugs through their listing of reimbursable drugs. Proof of this negotiating power lies in the fact that two provincial governments, in Quebec and Ontario, have imposed an unlegislated price freeze for several years. It is thus possible to obtain prices below PMPRB levels, whose guidelines provide for increases based on the consumer price index.

Finally, as we have already seen, there would be downward pressure on the prices of older patented drugs and non-patented drugs since distortions caused by price controls would cease to exist. It should be noted that non-patented drugs accounted for one-third of Canadian sales in 2002, which is far from negligible. Such a price structure would again reward pharmaceutical innovation and provide an invaluable service by saving patients and sometimes replacing more expensive hospital care. It would also contribute to economic dynamism in Quebec and across Canada. In contrast, maintaining administrative price controls over drugs seriously compromises the longer-term preservation of these beneficial effects on our quality of life.

¹⁴ PMPRB, *Op. cit.*, p. 53.

¹⁵ SECOR, *Op. cit.*, p. 29.

¹⁶ The Montmarquette Report's official name was *Pour un régime d'assurance médicaments équitable et viable. Rapport préparé par le Comité sur la pertinence et la faisabilité d'un Régime universel public d'assurance médicaments au Québec*, décembre 2001, p. 56.

¹⁷ Bandow, D., “Demonizing Drugmakers. The Political Assault on the Pharmaceutical Industry,” *Policy Analyst*, No. 475, 2003, p. 5 ; available at <http://www.cato.org/pubs/pas/pa-475es.html>.



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