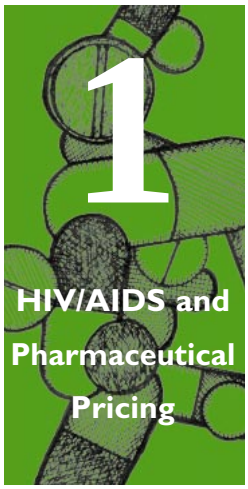

Health Spending and the Pharmaceutical Industry

This info sheet explains the importance of regulating prices of medicines, both for individual people living with HIV/AIDS and for overall spending on health care. It also provides a short overview of the pharmaceutical industry and market in Canada.

This info sheet is one in a series of seven info sheets on the federal regulation of pharmaceutical prices in Canada.

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Background

The cost of medicines is of obvious concern to people living with HIV/AIDS. Prices charged by pharmaceutical manufacturers are a significant component of the final cost to the purchaser. Globally, the price of medicines is receiving considerable attention amid efforts to increase access to treatment for millions of people living with HIV/AIDS or other health problems. In Canada, public and private spending on pharmaceuticals continues to rise dramatically, while a national debate on the future of the country's health-care system is ongoing. Canadians, including people living with HIV/AIDS, have a right to access affordable health care. This requires proper regulation of pharmaceutical prices.

Drug pricing and HIV/AIDS

The cost of treatment has increased significantly since the introduction of highly active antiretroviral therapy (HAART), due to the rising cost of the drugs, increased use of therapy, and the use of multiple drugs in combination. Treatment with HAART remains cost-effective overall, but the increase in spending is still cause for concern, for public and private insurance plans and for patients themselves, who incur greater out-of-pocket expenses.

In the absence of universal, public insurance coverage for pharmaceuticals across Canada, people living with HIV/AIDS rely upon a patchwork of private and public plans to pay for their prescription drugs. For many, these plans provide only partial coverage of the total cost of medicines. A 1999 Ontario study found that at least one in four people living with HIV/AIDS were carrying a substantial financial drug-cost burden. The study found that average out-of-pocket expenditure for a patient receiving ART in the province was $1629 a year, but that this could vary widely depending on who was paying for the drugs. High out-of-pocket expenses may occur for those whose insurance plan requires them to pay high deductibles, those who do not qualify for benefit programs, or those using drugs not approved by the programs.

Pharmaceutical spending in Canada

The price of pharmaceuticals is also a concern for Canadians more broadly. For the last two decades, spending on pharmaceutical products has been the fastest-growing component of total spending on health care in Canada. Since 1990, Canadian pharmaceutical spending per capita has doubled, from $191 annually in 1990 to $386 annually in 2000.

At least three major factors explain the increased spending on pharmaceuticals:

- the increased use of drugs on a per capita basis;
- the use of more expensive, new drugs rather than older, less expensive drugs; and
- the rising prices of existing drugs.

The Canadian Institute for Health Information (CIHI) estimates that spending on drugs outside hospitals (prescription and non-prescription) is the second largest component of health-care spending after hospitals. For 2002, spending on drugs is estimated to be $18.1 billion, or 16.2 percent of total health spending.

The most important component of this increase is spending on prescription medicines, which currently accounts for about three-quarters of total spending on pharmaceuticals. Furthermore, since the early 1990s, the share of spending on prescription drugs from private sources (private insurance companies, and patients themselves) has been over 50 percent. CIHI estimates that the figure is approximately 55 percent in 2002.

Pharmaceutical industry and sales in Canada

The pharmaceutical industry in Canada is composed of approximately 130 manufacturers of prescription medicines, including both firms that produce brand-name drugs and firms that produce generic copies of medications after brand-name patents expire. To a large extent, the brand-name drug industry in Canada is made up of foreign, multinational companies that have Canadian subsidiaries.

Concerns have been raised about the pharmaceutical industry in Canada, including the fact that over the last two decades Canada has quickly become heavily dependent on importing drugs to supply our pharmaceutical needs. In 1983, imports amounted to 18 percent of the Canadian market; by 2000, over 75 percent of the market was comprised of imports.

In the global picture, the smaller size of Canada's population and market means that, in 2002, sales in Canada represented only 2.6 percent of total worldwide sales by pharmaceutical manufacturers. However, sales of pharmaceuticals have been growing steadily in Canada, up to $13.1 billion in 2002. Sales of patented drugs now account for over two-thirds of total pharmaceutical sales in Canada, and the patented pharmaceutical sector has been among the most profitable in the country for many years.

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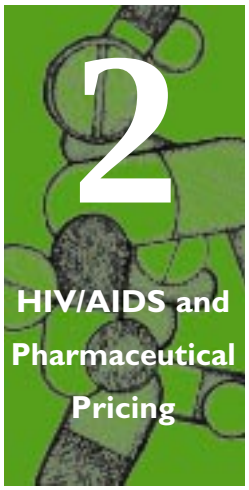

Controlling Medicine Prices: Evolution of Canadian Law

This info sheet gives a brief historical overview of how Canada has approached the question of regulating prices of pharmaceutical products, and the origins of Canada's current laws and policies.

This info sheet is one in a series of seven info sheets on the federal regulation of pharmaceutical prices in Canada.

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Pharmaceutical price controls are common

Like most developed countries, Canada has implemented public regulation of drug prices. But in some respects, Canada's approach to regulating the price of pharmaceuticals is unique. Canadian law regulating the price of pharmaceuticals has consistently, throughout its evolution over the past century, been tied to Canadian law and policy on patent protection for pharmaceutical inventions. This is still the case today, and policies regarding both pharmaceutical patents and prices are controversial. This is particularly so due to the overwhelmingly value Canadians place on equitable, universal access to health care.

Two approaches to regulating drug prices in Canada

Historically, Canada has adopted two principal approaches in its efforts to regulate the prices of patented medicines:

- compulsory licensing of pharmaceutical inventions; and
- direct regulation of pharmaceutical prices.

As is explained in more detail below, the approach has shifted over time from compulsory licensing to direct price regulation.

Compulsory licensing

A patent on an invention gives the patent holder the exclusive legal right to make use of, and to sell, the product that is patented (or the patented process for making a product) during the term of the patent. In other words, a patent is a temporary monopoly. From the 1920s to the 1980s, the federal government limited market monopolies – and the high prices that a company with a monopoly can charge – by limiting the scope and extent of patent rights in medicines. In other words, the law fostered market conditions that would limit prices of pharmaceuticals.

For several decades, Canadian law allowed for "compulsory licensing" in relation to medicines, allowing someone other than the company holding the patent to compete with lower-priced versions. Following legal amendments in 1969 that expanded the possibilities for compulsory licensing, there was a dramatic increase in the number of licences issued, which spurred the growth of a significant generic pharmaceutical industry in Canada.

In 1985, a federal Commission of Inquiry concluded that liberal use of compulsory licensing had saved Canadians hundreds of millions of dollars, had not adversely affected the Canadian research pharmaceutical industry, and had had little effect

on the decisions of multinational pharmaceutical companies regarding investment in research and development.

Price regulation

However, as described below, in the mid-1980s the federal government changed course. Rather than use its patent laws to promote market competition as a way of controlling the prices of pharmaceuticals, the government introduced a system for directly regulating the prices charged by manufacturers of patented medicines, to prevent them from abusing their patent rights by charging excessive prices. This is the system that remains in place today, and is administered by the Patented Medicine Prices Review Board (PMPRB). (See other info sheets in this series for more detail about the PMPRB and the pricing rules it enforces.)

Evolution of Canadian law: shifting the approach to pharmaceutical prices

In the 1980s, Canada began to change its approach to controlling the prices of medicines. One reason was pressure from the US during the course of negotiating the 1988 Canada/US Free Trade Agreement (FTA), to give greater patent protection to pharmaceutical companies. Given public concern about the impact this would have on the price of patented medicines, some alternative was politically necessary to prevent companies from using their monopolies to charge excessive prices. Therefore, the government moved to the current approach of imposing some controls on the prices of patented medicines. The changes to Canada's law happened in two stages: Bill C-22 in 1987 and Bill C-91 in 1992.

Bill C-22

In 1987, under pressure from the US during negotiations over the Canada-US Free Trade Agreement, the federal government passed Bill C-22 to amend Canada's Patent Act. The effect was to extend and strengthen the rights of patent holders, and to weaken and limit options for compulsory licensing. Bill C-22 made four major changes:

- First, the bill recognized patents on pharmaceutical *products* themselves, independent of a patented process for creating them. Previously, only *processes* for producing a medicine could be patented.
- Second, the bill extended the term of patent protection. Previously, the law gave patent protection for 17 years from the date the patent office granted the patent. Bill C-22 changed the patent term to 20 years from the date of filing the application for the patent. This change came into effect in 1989.
- Third, the bill introduced staggered periods of protection for a patent holder against the possibility of compulsory licensing for new medicines. Generic drug manufacturers could still obtain compulsory licences during the patent term, but these could not be used until a specified period of market monopoly for the original, patented medicine had expired. A compulsory licence could be used earlier if the generic medicine was made in Canada rather than imported.
- Finally, the bill created the Patented Medicine Prices Review Board (PMPRB), an independent body with the mandate to monitor drug prices and impose penalties in cases of excessive pricing by patent holders. This is now the principal way the federal government attempts to control pharmaceutical prices. (See other info sheets in this series for more detail about the PMPRB.)

Bill C-91

In the early 1990s, this time under pressure from the United States during the negotiations for the North American Free Trade Agreement (NAFTA), the federal government again amended Canada's patent laws. The amendments went well beyond the requirements of NAFTA. Bill C-91 was passed in 1992 and came into force in 1993. It made three major changes:

- It completely abolished the special rules on compulsory licensing of patented pharmaceuticals that had fostered the development of Canada's generic drug manufacturing sector in the 1970s and early 1980s. This means that pharmaceutical patent holders are now entitled to monopolies until their patents expire after a 20-year period. Canadian law still has some general rules about compulsory licensing (which can be done under some limited circumstances). These rules could be used for pharmaceutical inventions just as with other technologies. But there are no longer any special rules for dealing with medicines, which were intended to balance the interests of pharmaceutical companies with the rights of patients/consumers to affordable medicines.
- Bill C-91 also strengthened benefits for pharmaceutical companies holding patents on medicines in another way. The bill introduced regulations that link approval of a generic drug for sale in Canada to the patent status of the original drug. In order to legally sell a drug in Canada, the

manufacturer requires a "notice of compliance" (NOC). Under the "NOC regulations" passed under Bill C-91, if a pharmaceutical company simply alleges that a generic drug will infringe its patent on the original medicine, this automatically blocks the government from approving the generic drug for sale in Canada for up to 24 months. These regulations are open to manipulation by patent-holding companies in order to keep would-be competing drugs off the market. This is an exceptional rule that does not exist in any other circumstance in Canadian law, and has been criticized by the Supreme Court of Canada as "draconian" in its effect on generic manufacturers.

- Bill C-91 also reformed the powers of the PMPRB to monitor drug prices and prevent "excessive" pricing. It removed the PMPRB's power to expose a medicine to compulsory licensing if a company charged excessive prices, but gave it greater power to impose fines for failure to comply with orders.

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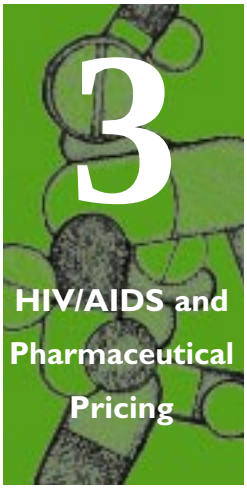

Patented Medicine Prices Review Board

This info sheet provides basic information about the Patented Medicine Prices Review Board, its mandate and functions, and the powers it has to enforce rules to control the prices manufacturers charge for patented medicines.

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What is the PMPRB?

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body created by the federal Parliament in 1987. It is independent of government, but reports annually to Parliament through the Minister of Health. The Board consists of five members appointed by the Cabinet, based upon recommendations from the Minister of Health and an advisory panel consisting of representatives of provincial health ministers, consumer groups, the pharmaceutical industry, and others appointed by the Minister. Board members serve on a part-time basis for five-year terms.

Mandate and functions of the PMPRB

The PMPRB "protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive." In fulfilling this mandate, the PMPRB carries out both *regulatory* and *reporting* functions:

- it monitors, and reports on, drug pricing, pharmaceutical sales, and the expenditure of patent-holding pharmaceutical companies on research and development (R&D) in Canada; and
- it regulates the prices charged by manufacturers of patented medicines to ensure they are not "excessive."

The Board's reporting function is important because it provides useful information for government and civil society organizations to monitor the pharmaceutical industry and to inform policy decisions and law reform. The obligation of pharmaceutical manufacturers to report annually to the PMPRB on their revenues and expenditures (including their spending on R&D) provides useful data. It also provides a mechanism for holding the pharmaceutical industry politically accountable to its commitments to increase spending in Canada on R&D.

Even more significant is the Board's regulatory function. In order to regulate medicine prices, the PMPRB collects data from drug manufacturers and applies a set of criteria in determining whether prices are "excessive." The PMPRB monitors and regulates both:

- the introductory prices of new patented medicines; and
- increases in the price of patented medicines after they enter the market.

Compliance and enforcement

Under the Board's Compliance and Enforcement Policy, Board staff investigate concerns about possible excessive pricing of a patented medicine. These concerns can be raised by the Board itself, or by complaints or information sent to the Board (eg, by a consumer advocacy group). If a price appears to exceed the Board's Excessive Price Guidelines, the manufacturer is given an opportunity to make a Voluntary Compliance Undertaking (VCU), in which the manufacturer undertakes to take steps to fix the problem, such as reducing the price. If the manufacturer does not make an undertaking, or its undertaking is not approved by the PMPRB Chairperson, then the Board may start formal proceedings and convene a hearing. If the Board finds that a company is selling the medicine at an excessive price, the Board may order the company to reduce its maximum price. The Board also has the authority to address past excessive pricing.

For more detail about the statutory criteria and the guidelines that the PMPRB uses in determining whether a manufacturer's price on a medicine is excessive, see info sheet 4 in this series.

Should the PMPRB's enforcement powers be strengthened?

When it was first created in 1987, the PMPRB could deal with excessive pricing or a manufacturer's failure to comply with its legal obligations or a PMPRB order by removing its protection against compulsory licensing of its patented medicine. Bill C-91 removed this enforcement power. (See info sheet 2, "Controlling Medicine Prices: Evolution of Canadian Law," for more detail about the history of these changes to Canada's laws on pharmaceutical patents and price controls.)

But Canada's obligations under international treaties (such as NAFTA or the WTO treaties) do not prevent it from integrating compulsory licensing into Canadian law. As long as Canada complies with the various conditions attaching to compulsory licensing required under those treaties, it is entitled to allow for compulsory licensing of pharmaceutical patents. This could be re-inserted into the Patent Act by granting the PMPRB the authority to issue a compulsory licence as a remedy for excessive pricing by patentees.

Recommendation

Parliament should amend the Patent Act to authorize the Patented Medicine Prices Review Board to issue a compulsory licence as a remedy for excessive pricing by a manufacturer of a possible patented medicine.

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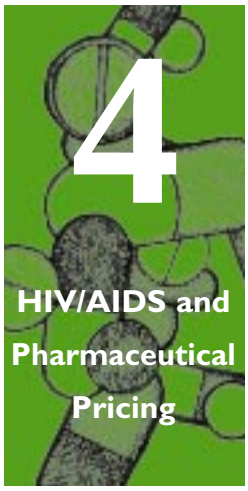

Preventing Excessive Pricing of Patented Medicines

This info sheet provides an overview of the rules applied by the Patented Medicine Prices Review Board to prevent manufacturers from charging "excessive" prices for patented medicines.

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Assessing pharmaceutical prices: the Patent Act

The Patented Medicine Prices Review Board (PMPRB) has the authority, under the Patent Act and the Patented Medicines Regulations, to monitor and regulate the prices charged by manufacturers of patented medicines in Canada to ensure that these prices are not "excessive." The PMPRB is required by the Patent Act and by regulations to consider the following factors:

- the prices at which the medicine has been sold in Canada;
- the prices at which other medicines in the same "therapeutic class" have been sold in Canada;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in seven other countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States); and
- changes in the Consumer Price Index (ie, inflation).

Assessing pharmaceutical prices: PMPRB guidelines

Based on these factors, the PMPRB has adopted "Excessive Price Guidelines." The Guidelines are applied in reviewing the introductory prices of every new patented medicine entering the Canadian market, as well as in reviewing price increases by manufacturers on existing medicines. A review includes a comprehensive scientific analysis, and comparisons of the price of the drug against other therapies and prices in other countries. The basic rules on pricing for both new drugs and existing drugs are explained below.

Regulating the introductory prices of *new* drugs

The PMPRB's Guidelines classify each new drug into one of three categories, and then apply various tests to assess whether the price being charged by the manufacturer in Canada is excessive. The three categories are:

- Category 1: a new formulation of an existing medicine. The usual rule is that the price must bear a "reasonable relationship" to the average price in Canada of other versions of the same medicine (reasonable relationship test.)
- Category 2: a new product that represent a therapeutic "breakthrough" or "substantial improvement" over existing drugs. For Category 2 drugs, the price can be as high as either one of the following, whichever is higher: (a) the highest price in Canada among all comparable drug

products (therapeutic class comparison test), or (b) the median of the prices charged for the same drug in the seven countries used for comparisons (international price comparison test).

- Category 3: a new drug, or new dosage form of an existing drug, providing moderate, little, or no improvement over existing drugs. For a drug in this category, the price is capped at the highest price in Canada of all comparable products in the same therapeutic class (therapeutic class comparison test). If this test cannot or should not be used for some reason, the PMPRB will usually limit the price to the median of the prices of that product in the seven other countries used for comparisons (international price comparison test).

Most "new" drugs offer moderate, little, or no therapeutic advantage (Category 3)

PMPRB data show that most "new" drugs do not offer any significant improvement over existing medicines. Out of 455 new patented drugs introduced into Canada from 1996 to 2000, only 25 of them (about 5 percent) were considered major improvements or "breakthrough" drugs. Over the last five years, over 75 percent of new products were deemed Category 3 drugs by the PMPRB, offering moderate, little or no improvement over existing drugs. These have been called "me too" drugs.

Category 3 drugs also account for the greatest proportion of pharmaceutical sales in Canada. And almost one-quarter of them are priced above the median international price level, according to a 1999 study by a joint committee of federal and provincial/territorial governments. The PMPRB is looking at how to give more weight, in its pricing guidelines, to the relative "value" of a new drug.

Regulating the prices of *existing* drugs

The PMPRB regulates the prices of drugs for the time they are under patent. Under the Board's Guidelines, the increase in the price of a patented drug is presumed to be excessive if it exceeds the rate of inflation as measured by the Consumer Price Index (CPI).

Prices of all patented drugs are capped using international price comparisons

In addition to any other tests for determining whether a price is "excessive," there is an overall cap on the manufacturer's price of any patented medicine sold in Canada. The manufacturer's Canadian price cannot exceed the price of the same drug sold in seven other countries: Germany, Italy, Switzerland, United States, France, Sweden, and the United Kingdom. In conducting international price comparisons, the PMPRB will compare the manufacturer's Canadian price for the drug with the simple average of the prices the manufacturer is charging for the same strength and dosage form in each of these seven other countries.

However, the approach could be improved by changing the countries that are used for international price comparisons:

- Canada lags behind many of these seven countries in the average time it takes to approve a new drug for marketing. This means prices are often set in comparator countries before they are in Canada – this includes countries that generally have higher pharmaceutical prices, such as the US and Germany, which do not have their own price controls. This pushes maximum allowable prices in Canada upward.
- These seven countries are not representative of countries belonging to the Organization for Economic Cooperation and Development (OECD) as a whole. They tend to have higher drug prices than several other developed countries. Choosing a different set of countries could significantly affect the maximum allowable price for a medicine in Canada. Some other countries that are more similar to Canada should be included in this set of countries used for international price comparisons.
- Patent-holding pharmaceutical companies spend less on research and development (R&D) in Canada than in most other industrialized countries, including most of the seven used for international price comparisons. This is the case even though the Conference Board of Canada reports that Canada offers "one of the most competitive tax systems for R&D in the world." According to the PMPRB, Canada accounts for a share of total pharmaceutical R&D spending worldwide that is only about half its share of total worldwide pharmaceutical sales. In other words, Canada is benefiting from only about half as much R&D spending by industry as the industry is benefiting from Canadian purchases of its products. Canadians are paying more than their fair share of global pharmaceutical R&D. So pricing rules that keep Canadian prices around the median of international pharmaceutical prices need to be re-examined.

Summary of PMPRB Guidelines

The overall effect of the PMPRB's Guidelines is that:

- prices for most new patented drugs are limited such that the cost of therapy for the new drug does not exceed the highest cost of therapy for existing

drugs used to treat the same disease in Canada;
- prices of new "breakthrough" patented drugs and those that bring substantial improvement are generally limited to the median of the prices charged for the same drug in other industrialized countries listed in the regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States);
- price increases for existing patented medicines are limited to changes in inflation; and
- for all drugs, the price of a patented drug in Canada may never exceed the highest price for the same drug in those seven foreign countries.

Recommendations

- The PMPRB should review whether the set of countries currently used for the purposes of international price comparisons is appropriate. The federal government should consider revising the list of countries used for these comparisons.
- The PMPRB, Health Canada, and Industry Canada should identify and assess options that would produce a closer correlation between overall Canadian price levels for patented medicines and levels of spending in Canada by pharmaceutical companies on research and development.

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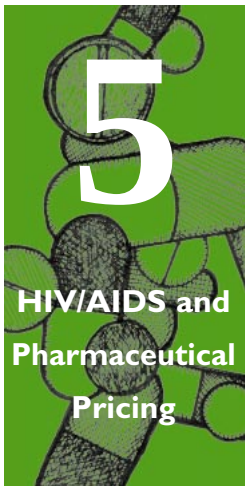

Jurisdiction of the PMPRB

This info sheet explains the scope and limits of the jurisdiction of the Patented Medicine Prices Review Board to regulate prices of patented medicines in Canada, and makes recommendations for strengthening that jurisdiction in the public interest.

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PMPRB jurisdiction: manufacturers' prices on patented drugs

Under the Patent Act, the PMPRB has jurisdiction to regulate prices charged by manufacturers of all patented medicines sold in Canada, both prescription and non-prescription. This includes regulating the price of each dosage form. If the company holding the Canadian patent on a medicine licenses that medicine, during the patent term, to another manufacturer for distribution in Canada (including a generic drug company), the PMPRB still has jurisdiction to regulate the price of the medicine while it is still under patent in Canada. The PMPRB only has jurisdiction during the term of the patent on a medicine. Once the patent expires, the PMPRB no longer has jurisdiction.

The price charged by the manufacturer is often referred to as the "factory-gate" or "ex-factory" price. This is the price set by the manufacturer for the first sale of the product to distributors, wholesalers, hospitals, and pharmacies. This price excludes sales taxes and markups by wholesalers or retailers along the marketing chain, which can significantly increase the final price paid by the purchaser. However, the PMPRB estimates that the manufacturer's factory-gate price still accounts for about 65 percent of the final price paid by consumers. This is why it is important to regulate the price at this stage.

The PMPRB has no jurisdiction over:

- the prices of non-patented drugs;
- price markups by drug wholesalers or retailers; or
- pharmacists' dispensing fees.

Challenges to the PMPRB's jurisdiction

Companies holding patents on medicines have attempted to avoid the jurisdiction of the PMPRB over their prices in several ways. These attempts have been largely unsuccessful. The Board itself has been assertive in staking out its jurisdiction, guided by the goal of consumer protection. Canadian courts have generally approved of this approach, on those occasions where they have been called upon to decide challenges to the PMPRB.

Regulating the prices of non-patented drugs

Unlike most developed countries that regulate drug prices, Canada only regulates the prices of *patented* drugs. Regulation has kept the prices of patented medicines in Canada at or slightly below the median of foreign prices in the seven countries the PMPRB uses for international price comparisons.

But with no regulation, the prices of non-patented drugs are significantly above the median of foreign prices.

There is good reason to regulate the prices of non-patented drugs in Canada as well. The higher prices of non-patented drugs have a significant impact on purchasers. In 1999, a joint committee of the federal and provincial/territorial governments reported that non-patented drugs represented about half the spending in provincial drug plans over the 1990-97 period. The Commission on the Future of Health Care in Canada (Romanow Commssion) has recommended regulating prices of all prescription drugs, whether patented or non-patented.

Non-patented drugs include all drugs for which the patent has expired, those drugs that are not yet patented or never will be, and generic drugs. Non-patented drugs may be "single-source" or "multiple-source":

- In the case of single-source drugs, the company holding the patent may still, after the patent expires, be the only company selling the product.
- In the case of multiple-source drugs, other manufacturers (such as generic companies) may be producing the drug after the patent expires. In addition, the company that originally held the patent, and therefore previously had a monopoly, may also still be selling its brand-name product.

Single-source non-patented drugs

In 1999, a joint federal and provincial/territorial committee reported that prices of single-source, non-patented drugs continue to be "substantially higher" – almost 30 percent higher – than the median international price among the PMPRB's seven comparator countries. The PMPRB reported in 2002 that average prices on drugs that are not patented, but were only available from one manufacturer, were higher in Canada than in all other countries except the US.

Multiple-source non-patented drugs

Even though, in the case of multiple-source drugs, there is competition in the market, prices in Canada continue to be high. The PMPRB has analyzed the prices of top-selling multiple-source medicines in Canada and the seven other countries it uses for international price comparisons. It found that the Canadian prices of the brand-name companies' drugs exceeded the median of foreign prices by 28 to 33 percent. This shows that, once the PMPRB can no longer regulate the price because the patent has expired, manufacturers of brand-name drugs have been successful in increasing prices even though faced with the legal possibility of competition from generic manufacturers. And while generic drugs account for a small portion of total drug sales in Canada (just under 14 percent in 2002), the PMPRB has reported comparatively high prices for generic drugs when compared to the median prices in other countries.

Recommendations

- Parliament should enact a national system for regulating prices of non-patented medicines to prevent excessive pricing, complementing the existing system regulating prices of patented medicines. Because of jurisdictional questions, different levels of government should collaborate to implement a consistent system across the country.

The information in this series of info sheets is based on Controlling Drug Costs for People Living with HIV/AIDS: Federal Regulation of Pharmaceutical Prices in Canada, a report prepared by the Canadian HIV/AIDS Legal Network. Copies of the report and the info sheets are available on the Network website at www.aidslaw.ca or through the Canadian HIV/AIDS Information Centre (email: aidssida@cpha.ca). Reproduction is encouraged, but copies may not be sold, and the Canadian HIV/AIDS Legal Network must be cited as the source of this information. For further information, contact the Network at info@aidslaw.ca. **Ce feuillet d'information est également disponible en français.**

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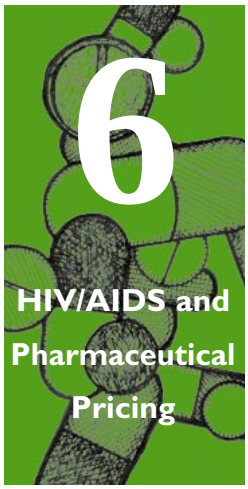

Pricing of HIV/AIDS Drugs

This info sheet summarizes the experience to date of trying to use Canada's regulatory scheme to challenge prices charged by manufacturers for some antiretroviral medicines used by people living with HIV/AIDS.

This info sheet is one in a series of seven info sheets on the federal regulation of pharmaceutical prices in Canada.

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CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

Canadian Strategy on HIV/AIDS

Complaints to the PMPRB about excessive pricing of HIV drugs

To date, activists with the Canadian Treatment Action Council (CTAC) have sought to contain the introductory price of four antiretroviral drugs. The first two cases have been unsuccessful. Decisions on the latter two cases were pending at the time of publication.

Efavirenz (Sustiva by DuPont Pharma)

Efavirenz (brand name Sustiva) is a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of HIV-1 infection. NNRTIs such as nevirapine and delavirdine already existed on the Canadian market at an annual cost of about $3000 per patient. Before efavirenz received final approval for marketing in Canada, DuPont Pharma advised the PMPRB that it intended to charge an introductory price of about $5000 a year. Considerably higher than the prices of existing NNRTIs, this price was in the range for protease inhibitors (PIs), another class of antiretrovirals for treating HIV, which sell at $5000-6000 annually per patient. This represented the first time an HIV drug in Canada was priced substantially outside the established range for its own class of drugs.

The PMPRB had provided non-binding advice to DuPont Pharma that its intended introductory price for efavirenz would be acceptable. In July 1999, CTAC filed a formal complaint regarding this advice and the manufacturer's intended price. Subsequently, with the patent still pending, the PMPRB advised DuPont that it should price efavirenz within the range of existing NNRTIs in Canada. DuPont rejected the advice as non-binding and maintained its original, higher price.

In 2002, the PMPRB concluded its price review of efavirenz as a Category 3 new drug, one that provides moderate, little, or no therapeutic advantage over comparable medicines. DuPont, however, argued that efavirenz is more effective in combination therapy than even protease inhibitors and can be an alternative to them – therefore, it should be allowed to price it at the higher level of protease inhibitors, rather than at a lower price comparable to other NNRTIs. The PMPRB accepted DuPont Pharma's argument that both NNRTIs and protease inhibitors could be used as appropriate "therapeutic class" comparators. Therefore, it decided that DuPont should be allowed to compare its efavirenz price to not just that of other NNRTIs, but also to protease inhibitors. This effectively meant the PMPRB dismissed CTAC's complaint.

Abacavir (Ziagen by Glaxo)

In August 1999, CTAC filed a formal complaint with the PMPRB alleging that Glaxo Wellcome (now GlaxoSmithKline) was charging an excessive price on its patented drug abacavir (brand name Ziagen). Abacavir is a nucleoside reverse transcriptase inhibitor

(NRTI) that Glaxo chose to price approximately 30 percent higher than other NRTIs.

As with efavirenz, the PMPRB classified abacavir as a Category 3 drug, meaning it provides moderate, little, or no therapeutic advantage over comparable medicines. And as with efavirenz, the Board concluded that the evidence showed that abacavir, although an NRTI, was an alternative to NNRTIs or PIs in combination therapy with other NRTIs. Therefore, it concluded that NNRTIs and PIs could be used as appropriate "therapeutic class" comparators, and so the price review of abacavir could take prices for these other classes of drugs into account. Again, this determination effectively dismissed CTAC's complaint.

Didanosine and lopinavir

In January 2002, CTAC filed formal complaints with the PMPRB regarding the prices of two other antiretroviral drugs. Videx EC is an enteric-coated formulation of the pre-existing drug didanosine, or "ddI," an NTRI patented by Bristol-Myers Squibb (BMS). Kaletra is the brand name for lopinavir, a PI patented by Abbott Laboratories. In both cases, CTAC alleges that the price set by the manufacturer fails the "reasonable relationship" test under the PMPRB's Excessive Price Guidelines, because the price is considerably higher than other medicines in the same class of drugs used to treat HIV infection. At the time of publication, decisions on both complaints were pending.

Revising the Excessive Price Guidelines?

Based on its experience to date with the pricing of Sustiva (efavirenz) and Ziagen (abacavir), CTAC has pointed to the dangers of basing drug prices on the comparative potency of one drug vis-à-vis another, regardless of its therapeutic class or research and development costs. CTAC is concerned that access to some drugs will be denied to Canadians. Provincial drug formularies will resist adding new drugs in a class where cheaper, approved drugs already exist, but people living with HIV/AIDS need all drug options because a one-size-fits-all approach does not work in treating HIV/AIDS. CTAC has recommended that drug pricing should be based on the actual costs of research and development, manufacturing, and other relevant costs, plus a reasonable profit.

In considering the potential therapeutic benefit of a new antiretroviral drug and in determining whether the manufacturer should be allowed to charge a higher price, the PMPRB can only use incomplete data. Therefore, its assessment does not fully reflect all the factors that should be considered in regulating prices. Data relied upon often comes from clinical trials that are of short duration and include small numbers of participants who are not necessarily representative of the actual population that will use the drug. Longer-term data, which can be applicable to a broader range of patients, on the durability and benefits of the drug, and on long-term toxicities, are not available.

In setting maximum allowable prices for new patented drugs, Canada's regulatory system will likely continue to take the therapeutic value of a drug into account to some degree. The system could be improved by creating a process for interim or conditional pricing of a new medicine upon its introduction to the Canadian market, with that price being automatically reviewed at appropriate periods over the life of the drug as more data become available to show a more complete picture of the drug's merits, and its merit relative to other drugs. The PMPRB could be given the authority to implement this kind of review and the authority to adjust the maximum allowable price as warranted by new developments.

Recommendations

- The PMPRB should revise its Excessive Price Guidelines such that maximum prices allowed to manufacturers of patented medicines bear a reasonable relationship to the cost of their development and manufacture, and allow a "reasonable" profit margin beyond those costs.
- Parliament should amend the Patent Act and/or the Patented Medicines Regulations to provide for a mechanism for interim or conditional pricing of a new patented medicine upon its introduction to the Canadian market, and to automatically review that price at appropriate periods over the life of the medicine to take into account new evidence regarding its therapeutic merits and its merit relative to comparator medicines. The PMPRB should be given the mandate and powers to conduct such reviews and to revise the maximum "non-excessive" price of a medicine as warranted by such new evidence.

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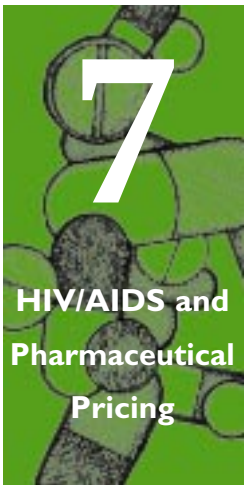

Trends in Pharmaceutical Prices, Sales, and R&D Spending in Canada

This info sheet presents basic information about trends in drug prices in Canada under price regulation. It also provides information about pharmaceutical sales, and spending on research and development by the patented pharmaceutical industry.

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Canadian Strategy on HIV/AIDS

Price trends: impact of regulation on Canadian medicine prices

Patented medicines

Evidence from Canada and from other countries indicates that regulation can contain medicine prices. When the PMPRB was created in 1987, Canadian prices were 23 percent higher than the median international prices, second only to price levels in the US. Since the mid-1990s, prices in Canada have remained consistently at about 10 percent below median international prices and in the mid range of European countries used as comparators.

More recently, the PMPRB has reported that:

- Since the mid-1990s, Canadian prices for patented drugs have remained between 5 and 12 percent below the median of foreign prices. In 2002, the prices of patented medicines in Canada were about 1 percent higher than the median of foreign prices in the seven countries used for price comparison purposes – lower than prices in the UK, Switzerland, and the US, but higher than those in Italy, France, Sweden, and Germany. As in previous years, US prices appear to be substantially higher than prices in Europe and Canada.
- Manufacturers' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), fell by 1.2 percent in 2002. This result continues the pattern of declines and near-negligible increases in the PMPI that began in 1993.

Non-patented medicines

Because prices of non-patented drugs are not regulated in Canada, and the PMPRB has no jurisdiction over them, there is no legally mandated, national system for gathering such data regarding drugs that are non-patented or about the generic pharmaceutical industry in Canada.

In September 2001, federal, provincial, and territorial ministers of health announced a project to monitor national expenditures on drugs. The National Prescription Drug Utilization Information System (NPDUIS), a joint effort between the PMPRB and the Canadian Institute for Health Information (CIHI), will provide more comprehensive monitoring of trends in price, utilization, and costs of pharmaceuticals, at least across public drug plans. This will generate some information for both patented and non-patented medicines.

However, it would be useful to have some across-the-board mechanism to provide more comprehensive data about the entire pharmaceutical industry in Canada, including generic companies, and not just data limited to the observable end results of price, utilization, and costs of drugs.

Sales and R&D spending by the patented pharmaceutical industry

Amendments to the Patent Act in the 1980s and 1990s gave pharmaceutical companies enhanced, legally

enforceable patent rights regarding their patented medicines. In exchange, they gave a collective and non-binding commitment to invest in R&D in Canada. Spending on R&D in Canada by multinational pharmaceutical companies increased from 1987 to 1997, the year Parliament conducted a review of the enhanced patent protections that was required by the patent law amendments. But since the 1997 review, the patented industry's spending on R&D in Canada, as a percentage of their total Canadian sales, has declined almost every year and is consistently well behind levels in all other comparable countries. Spending levels on basic research is an area of particular concern.

According to the PMPRB, in 2002 the R&D-to-sales ratio overall in the pharmaceutical industry remained at 9.9 percent in 2002, unchanged from 2001 for all patent-holding companies. In the case of companies belonging to Canada's Research-based Pharmaceutical Companies, the industry association for brand-name pharmaceutical companies in Canada, the ratio actually declined from 10.6 percent in 2001 to 10.0 percent in 2002.

The PMPRB has compared R&D spending and sales in Canada and the seven countries used for price comparisons. It reports that total sales in Canada of brand-name drugs accounted for 3.4 percent of total sales in these eight countries, but brand-name companies' spending on R&D in Canada amounts to only 1.8 percent of the total pharmaceutical R&D spending in these same countries. In other words, Canada was benefiting from only about half as much R&D spending by the patented pharmaceutical industry as the industry was benefiting from Canadian purchases of its products.

This suggests that stronger measures are required to ensure fair levels of R&D spending in Canada, in exchange for stronger patent protections and enhanced profits. Canada also has an opportunity to demonstrate its concern for global health, and for those in developing countries, by encouraging increased R&D into "neglected diseases." These are diseases principally afflicting poor people and the developing world, where the lack of adequate purchasing power means there is insufficient profit incentive for private pharmaceutical companies to invest in developing treatments for these diseases.

R&D spending vs marketing and promotion

The costs of R&D are regularly invoked as the primary justification for strong patent protections and accompanying high prices. But there are serious questions about the extent to which high drug prices are the result of what companies spend on marketing their products, rather than reflecting the cost of research and developing those medicines.

Canadian patent holders are required to report both their sales revenues and their spending on R&D. They are required to describe the "types" of R&D done, who did the R&D, capital expenditures on buildings and equipment, and the source and amount of the funds spent on R&D. However, there is no statutory requirement that they report to the PMPRB their spending on marketing and other promotional activities. This information would assist in weighing claims about the costs incurred by patentees in doing R&D versus promoting their products.

Recommendations

- Parliament should amend the Patent Act to require manufacturers of non-patented medicines to report annually on the details and sources of their revenues from sales of medicines in Canada. They should also be required to report details of their spending in Canada on pharmaceutical R&D.
- Parliament should amend the Patent Act to create legally binding requirements for R&D spending in Canada by patent-holding pharmaceutical companies. This could take the form of an annual levy on all patentees that do not meet a specified minimum ratio of R&D to sales. In addition, sales of all patented medicines should be subject to a levy, with the revenues dedicated to publicly funding basic research in Canada as well as research into "neglected diseases," in particular those prevalent in developing countries.
- Patent-holding pharmaceutical companies should include, in their annual reports to the PMPRB, a description of the type of promotional activities carried out and spending on each type of promotional activity. The federal government should amend the Patented Medicines Regulations to legally require reporting of this information.

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