

Making Treatments Accessible

**A Policy Paper on Determining Appropriate Pricing for
Brand-name Pharmaceutical Treatments for HIV/AIDS in
Canada**

Canadian Treatment Advocates Council

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Executive Summary

Advances in HIV/AIDS treatments in recent years have resulted in a remarkable improvement in the lifespan and quality of life of many people with HIV/AIDS. But the promise of treatment to extend and improve life is compromised by the ever-increasing prices of the pharmaceutical products.

This Paper examines the reasons pharmaceutical drugs are so expensive, the implications of higher prices, and some of the solutions to the problem. Its premise is simple: health care and life-saving treatments are fundamental rights that must not be compromised by the desire for unrestricted profits. The tools of public policy must be brought to bear to ensure these rights.

Canadian public policy on pharmaceutical drugs over recent years has seen a shifting balance between the protection of corporate rights – through government enforced patent protection – and the protection of public rights – through limits on patent protection or prices. Over the past 15 years, the balance has frequently shifted towards the former.

Despite the pharmaceutical industry argument that it has high research and development costs, the industry is not suffering financially. *Fortune* magazine ranked the brand-name pharmaceutical industry as the world's most profitable industry.

Drug costs are the most rapidly increasing component of total health care expenditures. In 1998 drugs accounted for 15.6% of total health care expenditures, more than the portion for physician services.

The market share for patented medicines has soared as generic products are banned from competition. Patented drugs in 1999 accounted for over 60% of drug sales in Canada, up from 43% in 1990.

Drug prices have a major impact for people with HIV/AIDS. The standard of care treatment for HIV disease is a 3 to 4 drug combination that must be taken indefinitely. A number of factors contribute to a highly profitable landscape for the pharmaceutical industry in development and sale of anti-HIV treatments.

The effectiveness of the Patented Medicines Prices Review Board (PMPRB) in restraining drug prices may be limited by a number of regulations, policies, procedures and practices. One important regulation is the schedule of the seven countries that are used to compare the introductory prices of new 'breakthrough' drugs in Canada to determine if the prices are excessive. Many critics argue that the list of seven countries does not reflect the appropriate comparable economies.

This paper proposes a number of principles and arguments that should guide public policy related to drug pricing:

- Health care is a right of all citizens.

- Patent rights must be constrained by the public interest.
- Price restraint was promised as a component of extended patent protection.
- Pharmaceutical corporations have benefited from public investment.
- Canada's relationship with the pharmaceutical industry should influence international drug prices.

The paper also proposes a number of recommendations to stakeholders to influence drug pricing. Among the key recommendations are:

Amend the *Patent Act* to:

- Reinstate compulsory licensing for drugs which treat life threatening or serious and chronic illnesses or for drugs which represent a significant treatment breakthrough (and which therefore have a captive monopoly market)
- Eliminate 'evergreening' – the practice of securing patents on different stages of the same product or on slightly different variations on a product.
- Expand the PMPRB mandate to include non-patented and generic medicines

Amend the *Patented Medicines Regulations* to:

- Amend the 'basket' of comparator countries to include a more representative sampling of economies
- Create a transparent review process that involves consumer and third party payer input
- Adapt the scientific review processes to include practitioners experienced with HIV/AIDS issues.

Amend the practices of the Patented Medicines Price Review Board to:

- Ensure fair and thorough comparison of drug prices within comparator countries
- Continue to include DVA and other discount USA prices when calculating the USA price comparison
- Provide expert reviews, relevant to the drug in question, on pharmaceutical companies' proposed 'therapeutic class' selection
- Provide avenues for consumer input into PMPRB rulings, and allow for consumer appeals. Publicize these avenues widely.

1. Introduction

The past five years have seen a dramatic change in the treatment landscape for people living with HIV/AIDS in the developed world. At least 15 antiretroviral drugs have come onto the marketplace, as well as a number of products to prevent or combat opportunistic infections, to boost the immune system, or to mediate the side effects of other treatments. Most of these treatments are taken in combination, in large quantities and for long periods of time.

The existing cadre of HIV treatments is insufficient: they do not work for everyone; they do not work indefinitely; they are inconvenient and unpleasant to consume; and they produce major side effects. However, the advances in treatment have resulted in a remarkable improvement in the lifespan and quality of life of many people with HIV/AIDS.

But the promise of treatment to extend and improve life is compromised by the ever-increasing costs of the pharmaceutical products. The cost is most immediately a barrier to those without (or with limited) insurance coverage. But spiralling prices threaten access to everyone because public and private insurance plans may choose to limit their liability by refusing to cover some drugs or by increasing user fees.

This Paper examines the reasons pharmaceutical drugs are so expensive, the implications of higher prices, and some of the solutions to the problem. Its premise is simple: health care and life-saving treatments are fundamental rights that must not be compromised by the desire for unrestricted profits. The tools of public policy must be brought to bear to ensure these rights.

This Paper uses the term *price(s)* to describe the price per unit of a product as determined by the manufacturer and as regulated by the government. We use the term *cost(s)* to describe the financial impact of the price and other factors on individual or collective buyers. For example, the *cost* of a prescription will depend on the *price* of the drug in question, the amount and duration of drug needed and the availability of alternatives. The *Patent Act* therefore affects the *costs* of drugs both by regulating the *prices* of patented drugs and by restricting the availability of alternatives.

This Paper was commissioned by the Canadian Treatment Advocates Council (CTAC) to support the Council's advocacy for accessible treatments for all Canadians living with HIV/AIDS. The author is grateful to a number of people who provided input into this paper, and is particularly thankful to: Antonia Swann, whose research and analysis into the issue proved invaluable; Dr. Joel Lexchin, a leading analyst of drug policy in Canada, who provided a substantive and thoughtful review; to Richard Elliott from the Canadian HIV/AIDS Legal Network for a detailed review; and to members of the CTAC Drug Pricing Committee who provided guidance and ongoing input.

2. History of Pharmaceutical Patent Protection in Canada

Canadian public policy on pharmaceutical drugs over recent years has seen a shifting balance between the protection of corporate rights – through government enforced patent protection – and the protection of public rights to affordable drugs – through limits on patent protection or prices. Over the past 15 years, the balance has frequently shifted towards the former.

In 1923 the *Patent Act* was amended, effectively introducing a compulsory licensing scheme in Canada. A compulsory license is a permit that effectively allows companies other than the patentee to manufacture and market their own version of a drug before the patent has expired. The Commissioner of Patents set a royalty fee that must be paid to the patent holder. However, the royalty fee was set at “the lowest possible price consistent with giving the inventor due reward for the research leading to the invention.” Food and pharmaceutical products were singled out for reduced patent protection under these amendments due to the fact that they were considered “public interest” goods.

For a number of years, the compulsory licensing system had a limited impact on reducing the price of pharmaceuticals due to several factors. One of them was that the generic licences were only available for products manufactured in Canada. Another was the fact that the size of the Canadian market and lack of export potential made it uneconomical to set up generic manufacturing facilities. Drug review requirements for generic competitors were also prohibitive.

In 1969 the government amended the *Patent Act* to support increased competition. The changes allowed for compulsory licensing for imported products, meaning that a generic company could get a compulsory licence even if it was importing the product into Canada. This meant significantly reduced costs for a generic company to market a product in Canada because the company did not have to do the manufacturing here. A sharp increase in the importation and manufacture of drugs by the generic industry followed. The manufacturing that was, and is, done in Canada post-1969 by generic (and multinational) companies is largely compounding, i.e., taking an imported active ingredient and making it into pills, tablets, liquids, creams, or other forms.

Following pressure to review the system by the brand name manufacturers, a Commission was established to review the compulsory licensing system, headed by Harold Eastman. The Eastman Report (1985) recommended retaining the compulsory licensing system, but with minor adjustments to strengthen the rights of patentees and to increase the royalty fees paid to them.

Despite the Eastman recommendation to retain compulsory licensing, the government brought in Bill C-22 in 1987. Bill C-22 established for the first time exclusive patent rights for between 7 and 10 years, depending on the circumstances of the patent. The length of exclusivity depended on whether the active ingredient was manufactured in Canada or not. If it was, the exclusivity period was 10 years; if it was imported, the

period was 7 years. The different exclusivity periods were intended to encourage local manufacturing in exchange for enhanced revenues through market exclusivity.

Bill C-22 also established the Patented Medicines Prices Review Board (PMPRB), with a mandate to ensure that prices of patented medicines were not “excessive” and to collect information from patentees regarding revenues and Research and Development (R & D) expenditures in order to determine their commitment to Canadian-based R & D in return for increased patent protection. With regard to drug prices, the PMPRB sets a maximum introductory price for new patented drugs. The formula for calculating the maximum price varies depending on the category of the drug. Once a patented drug is on the market, then effectively its price cannot go up more than the rate of inflation.

In 1993 the government further shifted the balance towards the brand-name pharmaceutical industry with Bill C-91, a Bill to amend the Patent Act. The government argued that the changes were necessary to comply with the provisions of the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA) regarding intellectual property rights.

Bill C-91 effectively ended the compulsory licensing scheme and introduced 20-year patent protection for pharmaceutical products filed on or after October 1, 1989. (The Bill provided 17-year patent protection – from the date the patent was granted - for products filed prior to October 1, 1989. The USA and European Union challenged the 17-year provisions through the World Trade Organization. An interim decision was rendered in May 2000 by the WTO, siding with the USA and European Union, and requiring Canada to extend patent protection to 20 years – from the date a patented is filed - for all patents. Canada appealed the decision, but in a ruling at the end of February 2000 the WTO upheld the decision. As a result, on February 20, 2001 the Canadian government introduced into Parliament Bill S-17, an Act to amend the *Patent Act*, that contains planned amendments to comply with the WTO ruling. It is expected to pass with minimal debate.)

Each of these shifts to increase corporate rights was met by vocal opposition from citizens’ groups arguing that the public interest of access to affordable drugs must be protected. (The shifts were also opposed by the generic drug industry, for business reasons). Government and industry countered that the shifts were necessary to encourage research and development, reward investment, and meet international trade obligations. They also argued that drug costs would not increase dramatically, and that those costs would be restrained by the powers of the PMPRB.

The industry, through the Pharmaceutical Manufacturers Association of Canada (now known as Canada’s Research-Based Pharmaceutical Companies) made a public commitment that the brand name pharmaceutical industry would increase its annual research and development expenditures as a percentage of sales to 10% by 1996 (from roughly 6%). They argued that this increased R&D expenditure would be accompanied by more industry jobs in Canada. They argued that prices for brand name products would not be unreasonably increased.

The Standing Committee on Industry reviewed the impact of Bill C-91 in 1997. Despite complaints from many citizens' groups that the extended patent protection had caused a significant increase in the cost of drugs, no major amendments resulted from the review. CTAC made a presentation to the Committee which argued, among other things, that the industry should be required to live up to its commitments on research and development, job creation and cost containment if patent protection was continued. The review did prompt a series of consultations by the PMPRB about its future, which culminated in a report called *Road Map for the Next Decade*.

3. The Impacts of Expanded Patent Protection in Canada

3.1 The Impact on Pharmaceutical Research & Development

Pharmaceutical manufacturers claim that significant patent protection is required due to substantial front-end research & development costs that must be recouped. The Canadian Research-Based Pharmaceutical Companies estimates it costs a minimum of \$750 million and 10 – 15 years to fully develop and market a drug.

This amount, according to health policy expert Dr. Joel Lexchin, is very misleading on a number of accounts.

- First it does not take into account tax breaks that companies get for investing in R&D. In Canada, depending on the province, companies are getting back about 40 cents on every dollar that they spend.
- Second, this figure includes “opportunity costs” i.e., money that was never spent. Opportunity costs are how much money could have been made by putting the money spent on research into other areas such as government of Canada bonds. Opportunity costs are a legitimate accounting technique but the industry does not use opportunity costs when it says how much money it puts into marketing.
- Third, this amount is money that is spent worldwide in developing new drugs, not money that is just spent in Canada. In fact, given the relatively small size of the Canadian market (2% of the world market) companies would never develop a drug just for the Canadian market.
- Finally, and perhaps most importantly, the \$750 million figure encompasses only a very small part of the universe of “new drugs”. The figure comes from the cost that American owned companies incurred in bringing to market new chemical entities that they developed entirely in house. That means that it excludes all new drugs that are not “new chemical entities”, all drugs developed by non-American owned companies, all drugs that were developed with assistance from government, hospital and other research, all drugs that were “licensed in” by American companies. “Licensing in” is where one company does the initial development work and then sells the rights to a second company. It is estimated that about 40% of the drugs introduced onto the American market are licensed in.

The brand-name pharmaceutical industry also argues that patent protection stimulates R&D investment, enhancing economic activity in the industry and domestic product development. Between 1963 and 1969, the annual R&D growth rate in Canada was 18%; after the effective implementation of compulsory licensing in 1969, it fell to 7%. It is not clear, however, if compulsory licensing was the main, or only, reason for the decline. For instance, a number of Canadian companies were sold to foreign interests that could have reduced R&D in Canada.

The patent protection afforded the brand-name pharmaceutical companies in Bills C-22 and C-91 was tied to commitments to increase R&D expenditures in Canada. The brand-name pharmaceutical industry promised to increase R&D to 10% of sales by 1996. The PMPRB monitors the industry’s progress on this, and reports that the promised ratios

have been met and exceeded. The sales to R&D ratio reported last year was 11.37%. Despite this reported increase, however, Canada still ranks low among industrialized countries in terms of R&D to sales ratio. PMPRB regulations identify seven countries for comparison with Canadian prices (USA, U.K., Germany, France, Sweden, Switzerland and Italy). Out of that list, Canada is at the bottom, tied with Italy, in R&D to sales ratio.

Several studies have noted that R&D expenditures in Canada are primarily applied research or pre-clinical and clinical research. Basic science research, where innovative breakthroughs begin, continues to represent less than 25% of total R&D spending in Canada. In 1999, basic science research declined as a share of total R&D expenditures to 18.4%, the lowest percentage since the PMPRB began reporting such information in 1988. This may mean that more resources are being devoted to product development but fewer new products are being produced.

Relatively few products introduced to the marketplace are “breakthrough” drugs (Category 2 drugs according to the PMPRB definition); in 1999 only one new medicine was classified as a Category 2 medicine, according to the PMPRB Annual Report. The brand-name pharmaceutical industry argues that these categorizations are made for pricing purposes and do not reflect the value of new drugs. However other studies suggest that the PMPRB figures are probably fairly accurate. A French drug information bulletin, *la revue Prescrire*, assesses the value of new drugs. Between 1981 and 1997 it looked at 1536 drugs; 7 were major therapeutic innovations in an area where previously no treatment was available; 60 were important therapeutic innovations with certain limitations; 149 had some value but did not fundamentally change the present therapeutic practice; 330 had minimal additional value and should not change prescribing habits except in rare circumstances; 850 did not add to the clinical possibilities offered by previously available products; 49 were without evident benefit but with potential or real disadvantages and 91 had their evaluations postponed.

Increased patent protection is only one contributing factor to increased R&D. Another is Canada’s favourable tax climate for R&D. The Conference Board of Canada concluded in a recent study that Canada maintains the most favourable tax system for R&D of eleven countries it studied.

Finally, industry critics are concerned that much of the increased R&D spending in Canada over the past decade has simply been a transfer of activity from the United States, facilitated by the industry’s commitments under Bills C-22 and C-91 and by the lower Canadian dollar. If this is true, the end result is of no greater benefit to drug consumers. Even the presumed benefit to Canada’s economy should be weighed against the social costs to health care access and the economic costs to consumers, public insurers and private insurers.

3.2 The Impact of Patent Protection on Industry Jobs

The brand-name pharmaceutical industry has argued that extended patents, and the resulting increase in R&D, increase economic activity and therefore employment.

Industry spokespersons report that they now employ almost 20,000 people, up 35% in the past decade (although this depends on which year is taken as the base year). This argument is perhaps more effective with politicians whose ridings include brand-name manufacturing activity than with those whose ridings include generic manufacturers. The increase in brand-name industry employment has been offset, somewhat, by lost employment opportunities in the generic manufacturing and sales sectors.

Other critics, such as the Canadian Labour Congress, note that many of the new jobs have been in areas of sales, marketing, and promotion rather than research and development.

3.3 The Impact of Patent Protection on Industry Revenues and Profits

Critics of the pharmaceutical industry's position note that, despite claims of high R&D costs, the industry is not suffering financially. *Fortune* magazine, in its April 2000 issue, ranked the brand pharmaceutical industry as the world's most profitable industry.

According to the Eastman Report, even before Bill C-91, brand-name manufacturers enjoyed a healthy return on equity of approximately 36%. A generally accepted good rate of return is about 15%. The Eastman Report states that the compulsory licensing system in place prior to Bills C-22 and C-91 did not hurt the profitability of the pharmaceutical industry and that, while the generic industry experienced significant growth after the 1969 amendments, by 1983 the patent industry had lost only 3.1% of its market share. As noted in the Eastman Report, numerous provinces instituted generic substitution policies following the 1969 amendments to take advantage of the market competition generated by compulsory licensing. Even with a federal regime allowing compulsory licensing, and provincial regimes promoting generic substitution, the brand-name pharmaceutical industry remained highly profitable.

Perhaps the profitability of the industry stems from the unparalleled demand for its products. Unlike many consumer goods, brand-name pharmaceutical goods are (or are believed to be) essential elements in maintaining health, with few alternatives available (or believed to be available) thanks in part to patent protection. Prices are certainly more reflective of that captive market than of other factors. The factory-gate price of drugs does not reflect the cost of production. And an AIDS Action (a coalition of USA advocate groups) study of the 15 largest pharmaceutical companies in the USA found that pharmaceutical companies collectively spend nearly three times as much money on marketing and administration as on research and development. The latest USA figures on promotional expenses (NY Times 17 Nov 2000) are \$13.8 billion annually. In Canada, Dr. Joel Lexchin estimates that the industry spends about \$1 billion per year on promotion.

Industry profits show no sign of diminishing. World pharmaceuticals sales in 12 leading markets grew by 10% in 1999, the first double-digit increase for a number of years and a substantial increase over the 6% growth seen in 1998. Total retail sales for the year were USA\$207.5 billion. Between 1980-87 the rate of return on shareholder's equity in the

pharmaceutical industry in Canada was 36.8% versus 14% for all manufacturing industries; between 1988-95 the figures were 29.6% versus 10.7%, respectively.

Sales figures in Canada have seen even more dramatic increases. Total sales of all drugs in Canada increased by 16.8% in 1999 to \$8.9 billion. Sales of patented drug products increased in 1999 by 27% to \$5.4 billion.

The pharmaceutical industry argues that its present prices are determined by including R&D costs in the price. It also argues that R&D for drugs would not be financially sustainable without a lengthy period of patent protection at this price. While it is acknowledged that there should be reasonable patent protection, the factors mentioned above counter the argument that present prices are always necessary to recoup R&D costs.

3.4 The Impact of Patent Protection on Overall Cost of Drugs

Not surprisingly, extended patent protection has had an impact on the cost of drugs in Canada. Overall drug costs have escalated in large part because fewer generic products are now allowed to compete with brand name products that now enjoy extended patent monopolies. Also, by the time generics appear the sales of the brand name product may well be in decline and therefore the potential savings from generics is less than when compulsory licensing existed.

The market share for patented medicines has soared as generic products are banned from competition. Patented drugs in 1999 accounted for over 60% of drug sales in Canada, up from 43% in 1990.

Generic drug prices are an average of 50% less than patented drugs, according to the Canadian Drug Manufacturers Association. A Green Shield Canada study found that, since 1988, the average cost of claims for patented drugs rose 13.4% annually compared to 7.5% for non-patented drugs. The study attributed the increases to the introduction of more expensive patented drugs to replace older, less expensive drugs. Between 1993-97 the average cost of a prescription for a new patented drug went from \$36.03 to \$76.88. By comparison the cost of a prescription for an existing patented drug went from \$49.43 to \$63.70 and the cost for a prescription for an unpatented drug (which would include generics) went from \$17.12 to \$20.10.

The Eastman Report indicated the previous compulsory licensing system saved Canadian consumers \$211 million in 1983 alone. Several studies have suggested that the elimination of the compulsory licensing regime has cost the health care system hundreds of millions of dollars; one 1997 study by Anderson et al from Queens University estimated that enhanced patent protection could cost consumers between 3.7 and 6.0 billion dollars.

3.5 The Impact of Patent Protection on Prices of Individual Products

While the *overall cost* of drugs has increased substantially because of the extended ban on generic competitors, the *prices of individual* patent drugs have increased at a moderate pace.

Prices for patented drugs have increased by an average of 0.8% per year since 1988, considerably below the 2.6% average increase in the Consumer Price Index. It is also well below the 1.9% average increase in patented and non-patented drugs combined.

In comparison, drug prices in the United States increased in the same period by an average of 5.1%. Since 1987, Canadian prices for patented drugs have declined over 30% compared to prices in the seven countries listed in the *Patented Medicines Regulations*. Of the seven, Canadian prices rank third lowest: below Sweden, Germany, the United Kingdom, Switzerland and the USA; and above Italy and France.

While the price controls in the *Patent Act* as monitored by the PMPRB have no doubt contributed to the moderation in individual product price increases, they are not the only factor. Market conditions may well have had a dampening effect on prices. In particular, the 'bulk-buying' and other practices of provincial drug plans have helped keep prices under control. Provincial drug plans account for 30% to 40% of all prescription drug sales in Canada, which gives them substantial negotiating power. Provinces have been known to refuse to purchase products they believed were overpriced. USA States cannot exercise the same bargaining power because they do not purchase drugs. Even the bulk-buyers that do exist, such as managed care organizations and the Veterans Administration, do not account for the same portion of that country's market as provincial drug plans account for in Canada, according to a May 16, 2000 article in the *Globe & Mail*.

3.6 The Impact of Patent Protection on Public and Private Insurers

Public drug programs are responding to the increased cost of prescription drugs by implementing a variety of cost-control mechanisms, including restricting formularies, placing some drugs in special access programs or requiring consumers to share the burden of the cost. British Columbia, for example, introduced reference-based pricing (see further explanation on page 20 of this Paper) as a way of containing the increasing cost of drugs.

User fees have a very dramatic effect on the most vulnerable segments of society. When Quebec reformed its system of drug insurance it imposed user fees on social assistance recipients and the elderly. The result for the elderly was: 35% more hospitalizations, 13% more physician visits and 50% more emergency department visits. For social assistance recipients the figures were: 194%, 22% and 106%, respectively.

A Federal/Provincial/Territorial Pharmaceutical Issues Committee (PIC) was established in late 1998 to review pharmaceutical issues as a component of the Canadian health care

system, including drug prices, drug utilization and system efficiencies. Some of their preliminary results on Drug Prices and Cost Drivers, 1990 – 1997:

- The 6 provincial drug plans studied saw a 44% increase in expenditures over this time period; changes of utilization of existing medicines and the introduction of newer, more expensive drugs accounted for the majority of the increase
- A cost driver analysis of the BC pharmacare system indicated that by 1997, newer drugs (those introduced since 1990) accounted for 57% of pharmacare spending.

Private insurers are similarly responding by raising premiums, capping drug coverage at monthly, annual or lifetime rates, and increasing employee deductibles.

A Conference Board of Canada survey indicated that 81% of businesses report that the rising cost of drugs is the number one factor driving up the costs of their health plans.

3.7 The Impact of Patent Protection on Consumers and Their Health

Drug costs are the most rapidly increasing component of total health care expenditures. Health Canada reported that in 1998 drugs (including in-hospital drugs, prescription drugs, non-prescription drugs, distribution fees and pharmacists' dispensing fees) accounted for 15.6% of total health care expenditures. This is more than the portion for physician services.

The National Forum on Health Report (1997) estimates that over 20% or more of prescription drug costs are borne by individuals with neither public nor private drug coverage. Privately paid drug expenditures is the largest category and fastest growing category of private health spending in Canada. The poor spend a much greater proportion of their income on prescription drugs than the wealthy. According to a study by Dr. Joel Lexchin, in the period 1984-1990, as a percentage of total expenditures the out of pocket expenditures for the two lowest income groups was 7 times more than the out of pocket expenditures for the two highest income groups. In absolute dollars, out of pocket expenditures for the two lowest income groups was higher than for the two highest income groups.

Rising prescription drug costs contribute to the necessity of cutbacks in other health care services. In theory, public health care spending could be shifted to drugs from acute care. In reality all health care costs – such as drugs, physicians, and hospitals - continue to grow beyond the willingness of governments to provide adequate funding.

Proper use of drugs can result in savings in other health care cost, such as hospitalization and doctor visits. But this is a moot point if people cannot access drugs because of their costs.

4. The Specific Impacts on HIV

4.1 The Impact on HIV – Cost of Drugs

The standard of care treatment for HIV disease is a 3-4 drug combination (not including prophylaxes) which must be taken indefinitely. The monthly cost of an antiretroviral regimen can be over \$1,500, not including prophylaxes for opportunistic infections and medications to deal with side effects. Increasingly, HIV affects socioeconomically disadvantaged communities, which have traditionally faced more challenges in accessing health care.

The high cost of HIV antiretroviral regimens (\$20,000/annum and higher) has forced some individuals to leave workplaces without drug plans, in order to access provincial drug formularies through social assistance programs.

Pre-existing condition clauses in private insurance policies often exclude people living with HIV/AIDS from drug coverage. This forces people to rely on public plans, pay for the drugs themselves, or do without them. Insurance policy restrictions also result in “job-lock”, where people with HIV who have drug benefit coverage are forced to stay in their jobs for fear of being excluded from other benefit plans.

4.2 The Impact on HIV – Profitability for the Pharmaceutical Industry

A number of factors contribute to a highly profitable landscape for development and sale of anti-HIV treatments.

- The market (number of people living with HIV) is constantly growing and the growth shows no sign of slowing.
- It is a captive market. Anti-HIV treatments are in fact a matter of life or death for people with HIV.
- It is a long-term market. Unlike many pharmaceutical products, most antiretroviral drugs are designed for long-term, even life-time consumption.
- Competitive products can *increase* rather than decrease the market. The combination therapy approaches – unusual in disease management – mean that a new competitor in the antiretroviral market can be an adjunct, rather than a replacement, to an older drug.
- R&D costs are heavily subsidized by taxpayers. Research costs for all pharmaceutical products are supported by public funding for research infrastructure (e.g. universities). In the case of HIV therapies, even more components of R&D costs are taxpayer supported, for example, the AIDS Clinical Trial Group in the USA and the Canadian HIV Trials Network. Direct tax deductions for R&D provide further public subsidies.
- The accelerated review process for many HIV therapies means that companies get their products onto the market faster. This means, in some cases, that instead of it taking 7-8 years after discovery to get a drug onto the market it may take 5-6 years.

This means that companies enjoy a monopoly position for 14 to 15 years instead of 12 or 13 years.

- Expanded access programs (which bear a cost to the manufacturer, but which is written off as business cost) provide an instant market of dependent consumers the day the product is licensed.

To illustrate the profitability of anti-HIV drugs, Burroughs Wellcome (now GlaxoSmithKline) more than recouped its R&D investment in AZT in the first year of sales alone. Considering the vastly expanded market over the past decade, it is likely that profit margins are just as robust today.

4.3 The Impact on HIV – Recent Concerns on Exorbitant Prices

Concerns have been expressed that new HIV drugs coming onto the market are being priced well above what they should be given prices for other drugs in their therapeutic class. For example, the manufacturers of Ziagen (abacavir), a nucleoside reverse transcriptase inhibitor, and particularly SUSTIVA (efavirenz), a non-nucleoside reverse transcriptase inhibitor, have been criticized for their proposed prices, both in the USA and Canada. SUSTIVA costs approximately 40% more than other drugs in the non-nucleoside class; Ziagen costs approximately 30% more than other drugs in the nucleoside class.

5. Stakeholders' Role in the Cost of Drugs

5.1 Sellers - the Pharmaceutical Industry

The global pharmaceutical industry is dominated by a number of large multinational enterprises based in several countries. Most of these companies have Canadian subsidiaries which, along with a few domestic pharmaceutical firms, account for the vast majority of the manufacture, sale and distribution of drugs in Canada. It has been reported that the top ten pharmaceutical companies accounted for approximately 50% of total sales in Canada in 1999, similar to the proportion in 1998. Of the top ten firms, one was a Canadian company supplying generic products.

According to Statistics Canada, the pharmaceutical industry accounted for less than 2% of all sales and employment in the manufacturing sector of the Canadian economy in 1997. The industry employed 20,000 people, reported to be a 35% increase over the past decade. The industry is estimated to account for approximately 10% of total R&D. The R&D portion is consistent with this industry's relative performance since 1987.

Canada's Research-Based Pharmaceutical Companies (CRBPC), formerly the Pharmaceutical Manufacturers Association of Canada, represents 60 companies in the industry.

5.2 Regulators - Ministry of Industry - Federal Government

The Ministry of Industry is mandated to enforce the *Patent Act*, except for the sections pertaining to patented medicines.

5.3 Regulators - Ministry of International Trade – Federal Government

The Ministry of International Trade is mandated to lead negotiations on, to enforce adherence to and to respond to challenges related to international trade agreements such as the Trade Related Aspects of Intellectual Property Rights and the North American Free Trade Agreement.

The Ministry has recently lost an appeal a World Trade Organization ruling that extends pre-1989 patent rights from 17 to 20 years.

5.4 Regulators - Health Canada - Federal Government

The Minister of Health is designated under the *Patent Act* with responsibility for the sections of the Act pertaining to patented medicines, including the Patented Medicine Prices Review Board (PMPRB). The Minister of Health develops the *Patented Medicines Regulations* to regulate the actions of the PMPRB. The PMPRB reports to Parliament through the Minister of Health.

Health Canada, through its Therapeutic Products Directorate, also assesses new medicines to ensure that they conform to the *Food and Drugs Act* and *Regulations*. Formal authorization to market or distribute a medicine is granted through a Notice of Compliance (NOC) or Notice of Compliance with Conditions. A medicine may be temporarily distributed with specified restrictions before receiving a NOC, as an Investigational New Drug or under the Special Access Program.

The review process for pharmaceutical products (brand name and generic) is designed to ensure that they are safe and effective for the indications claimed. It is also designed to ensure that the drugs are manufactured under appropriate conditions. Health Canada regulations also restrict the advertising of pharmaceutical products to consumers.

Health Canada's Therapeutic Products Programme does not directly regulate the price of pharmaceutical products. However, the laws and regulations surrounding compassionate access programs, clinical trials, and the speed of regulatory approval all have an impact on the final price of the products.

Health Canada also enforces the *Canada Health Act*, as a result of which the provinces must provide hospital care, including in-hospital drugs, to all Canadians without charge.

5.5 Regulators - Patented Medicine Prices Review Board – Federal Government

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body created by Parliament in 1987 under the *Patent Act*. The PMPRB “protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive,” according to its 1999 Annual Report.

The PMPRB is regulated by the *Patent Act* and the *Patented Medicines Regulations*. It has developed its own *Compendium of Guidelines, Policies and Procedures* in consultation with stakeholders including governments, industry and consumer groups. In addition, the Board has issued a number of documents on interpretation of its guidelines.

The PMPRB reports to Parliament through the Minister of Health. The Annual Report, which covers each calendar year, includes a review of the PMPRB's major activities, analyses of the prices of patented medicines and of the price trends of all drugs, and reports on the R&D expenditures by patent-holding drug manufacturers.

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use to ensure that they are not excessive. If, after a public hearing, the Board finds that a price is excessive it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received. In most cases the price reviewed by the PMPRB is the “factory-gate” price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The PMPRB's jurisdiction includes patented medicines marketed or distributed under voluntary licenses. The PMPRB has no authority to

regulate the prices of non-patented drugs, including generic drugs, and does not have jurisdiction over prices charged by wholesalers or retailers nor over pharmacists' professional fees.

The PMPRB's Price Guidelines are based on the price determination factors in Section 85 of the *Patent Act* and on the *Regulations*. In summary, the Guidelines provide 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 breakthrough patented drugs and those which bring a substantial improvement are 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, U.K., and USA);
- Price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and
- The price of a patented drug in Canada may, at no time, exceed the highest price for the same drug in the foreign countries listed in the *Regulations*.

5.5(a) PMPRB Issue – The Comparison Countries

The seven countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States) selected by the *Regulations* as the “basket” of countries with which to undertake price comparisons have some of the highest drug prices in the world and are therefore not accurate indicators of median world drug prices. The USA, for example, consistently has by far the highest drug prices in the world.

There are other countries not listed with many more similarities to Canada in health care delivery structures and other infrastructures. Australia is an obvious example.

Almost all patent drug manufacturers in Canada are branches of large multinational firms. These firms have the opportunity to set their prices in other OECD countries prior to establishing the factory-gate price in Canada, partly because Canada is slow in its review process. As a result, the international price comparisons used by the PMPRB are, in many cases, already established by the pharmaceutical firms, based on their estimate of what the market can bear under the regulatory regimes of other jurisdictions.

5.5(b) PMPRB Issues: Drug Prices Within Comparison Countries

Even within the ‘basket of 7’, international price comparisons can be influenced by the prices chosen for comparison from within other countries. For example, the USA Department of Veteran Affairs purchases drugs at a discounted cost (apparently with little harm to the industry's profit margins). The PMPRB has only recently agreed to include these discounted prices as part of the calculation of the international price comparison.

5.5(c) PMPRB Issues: Defining Therapeutic Classes of Drugs

The PMPRB's review of new drugs in relation to their 'therapeutic class' can also be problematic. In 1999 Dupont Pharma requested non-binding advice from the Board on its antiretroviral product SUSTIVA while the patent was pending. The Board initially agreed with Dupont's proposal that SUSTIVA was comparable with protease inhibitors rather than its actual category, non-nucleosides. The decision would have allowed SUSTIVA to be priced at double that of its therapeutic class. After the AIDS community, led by CTAC, provided arguments against this decision, the Board rescinded its non-binding advice and recommended that Dupont price the drug in the same range as other non-nucleosides. The Board also initiated a review involving experts in HIV/AIDS. (Dupont, which relied on the first non-binding advice to support its price, has refused to rely on the second decision and lower its price, pending patent approval).

5.5(d) PMPRB Issues: Expert Advice

The case above may illustrate a procedural flaw for PMPRB. Although manufacturers wishing to have a "breakthrough" or Category 2 drug must file a submission to the Board's Human Drug Advisory Panel – which can subsequently seek additional expert advice – it is not clear what level of expertise is involved in assigning drugs to therapeutic classes. Given the complexities of HIV treatment, antiretroviral products may in particular require specialist expertise to assess.

5.5(e) PMPRB Issues: Appeals

There are clear provisions for Board decisions to be appealed by the affected pharmaceutical company. Other stakeholders can, if they feel that a drug is priced too high, file a complaint with the PMPRB that will then investigate the situation. However, this appeal process is not well publicized.

5.5(f) PMPRB Issues: Evergreening

It is possible for a pharmaceutical company to file several patents on the same product over the period of patent protection, thereby extending the patent on the medicine each time. Manufacturers can produce essentially the same drug, but make small changes in the way it is manufactured, for example, by changing the dosage, formulations or manufacturing processes. This practice is known as "evergreening" and has been criticized by consumer advocates as a way of extending patent protection well beyond the intent of the legislation.

5.6 Buyers - Third Party Payers

Third party payers for drugs, most notably provincial drug plans and private insurance companies, can influence the price of drugs by negotiating bulk price discounts. In more drastic situations, they can refuse to cover expensive products or limit coverage of them only in extraordinary circumstances. These tactics often result in lower 'factory gate' prices from the manufacturer, which lowers the price for all buyers.

British Columbia has instituted 'reference based pricing' for its provincial formulary. The B.C. government has selected 5 categories of drugs (H2 blockers, NSAIDs, long-acting nitrates, ACE inhibitors and dihydropyridine calcium channel blockers) where the evidence says that all of the products are equally safe and effective. In each of these classes the government has designated a reference product (usually the least expensive) and no matter which drug in that class has been prescribed the government will only pay the reference price. If patients want another drug in the class they have to pay the difference between the reference price and the price of the product. If there is a medical need for a product other than the reference product then the patient's doctor can fill out a form and the other product will be fully covered

Ontario has developed a 'limited-use program' that restricts access to roughly 180 expensive new products. Physicians wishing to prescribe them under the program must justify each prescription with information provided to Ministry of Health officials. The amount of information that has to be provided has been greatly reduced recently. Doctors have to write the prescription on a special prescription pad and include a code number that says why the particular drug is being used.

5.7 Buyers - Citizen Groups

A wide array of consumer, medical, labour and other groups have spoken out against extended patent monopolies for health products. They have also called for more effective restraint of pharmaceutical prices.

6. Principles for Drug Price Restraint

6.1 Health care is a right of all citizens.

Canadians have consistently expressed a desire for publicly funded, universally accessible health care. It is inconsistent with this principle to have a major (and growing) component of the health care system beyond regulation. It is also inconsistent with this principle to have a major component of the health care system beyond access. This is particularly true for those pharmaceutical products needed to preserve the health of those with life-threatening illnesses. Patients with catastrophic illnesses are different from the rest of the patient population in that they face imminent death. The freedom of people to save their own lives has been granted fundamental importance in the legal and ethical systems of western society.

6.2 Patent rights must be constrained by the public interest.

Due to the fact that pharmaceutical products are essential for saving or extending lives, they are unique in the way that other products are not and should therefore be treated differently in terms of patent protection. The fact that pharmaceuticals are essential products for maintaining health or saving lives can lead to price inflexibility and extraordinary cases of price-cost discrepancies. International trade agreements recognize the right of nation states to preserve the public interest. There are options within international trade agreements that allow for a compulsory licensing system and parallel importing in certain circumstances.

6.3 Price restraint was promised as a component of extended patent protection.

During public debates during the introduction of both Bill C-22 and C-91, government and industry representatives assured the public that prices would not unduly rise and that the PMPRB would be empowered to ensure the public's interest. Thus price restraint is part of the 'social contract' that provides patent protection.

6.4 Pharmaceutical corporations have benefited from public investment

This public investment should be rewarded by prices that reflect the public interest. Indeed, patent protection itself is both granted and enforced by the state. Public funds support indirect infrastructure (e.g. roads, security, workforce education), indirect infrastructure (e.g. universities) and direct research and development (e.g. Canadian HIV Trials Network) costs of the pharmaceutical industry. Revenue Canada grants investment tax credits for qualifying R&D costs of up to 20% if the firm is foreign-controlled and up to 35% if the multinational firm partners with a Canadian-owned firm. Provinces grant additional tax credits. The Conference Board of Canada concluded in a recent report that Canada maintains the most favourable tax system for R&D of eleven countries it studied.

6.5 Canada's relationship with the pharmaceutical industry could influence international drug prices.

Canadian recognition that the public interest takes priority over the supremacy of corporate rights could provide leadership to other countries that are unable to provide health care to their citizens. The presumed sanctity of free trade must be challenged when lives are at stake.

7. Recommendations

7.1 Recommendations for Pharmaceutical Industry

Industry should consult with affected stakeholders as part of its process for PMPRB price approval.

7.2 Recommendations for the Ministry of Health

7.2(a) Amend the *Patent Act*

- Reinstating compulsory licensing for drugs which treat life threatening or serious and chronic illnesses or for drugs which represent a significant treatment breakthrough (and which therefore have a captive monopoly market)
- Eliminate ‘evergreening’ – the practice of securing patents on different stages of the same product or on slightly different variations on a product.
- Expand the PMPRB mandate to include non-patented and generic medicines

7.2(b) Amend the *Patented Medicines Regulations*

- Amend the ‘basket’ of comparator countries to include and/or replace with a more representative sampling of economies
- Create a transparent review process that involves relevant stakeholder input including consumer and third party payer input
- Adapt the scientific review processes to include practitioners experienced with HIV/AIDS issues.

7.3 Recommendations for the Ministry of International Trade

- Continue to appeal WTO and NAFTA rulings that restrict Canada’s ability to direct its health care.
- Reject international trade agreements that limit the Canadian government’s ability to adhere to the Canada Health Act.
- Ensure that all international trade negotiations place human rights (including the right to health) before private property interests, and that all trade agreements expressly state that in the event of a conflict between government action intended to fulfil its obligations under international human rights law and an obligation imposed on it by other provisions of the trade agreement, its human rights obligations supersede trade obligations.

7.4 Recommendations for the PMPRB

- Ensure fair and thorough comparison of drug prices within comparator countries.
- Continue to include DVA and other discount USA prices when calculating the USA price comparison.
- Provide expert reviews, relevant to the drug in question, on pharmaceutical companies’ proposed ‘therapeutic class’ selection

- Provide avenues for consumer input into PMPRB rulings, and allow for consumer appeals. Publicize these avenues widely.

7.6 Recommendations for Third Party Payers

Work to develop a ‘common front’ among provinces to negotiate prices with the industry.

7.7 Recommendations for Citizen Groups

Consumer activism has been a deciding factor in influencing both broad legislation and specific pricing decisions. Citizen groups should continue to form alliances and exert political pressure on industry and governments nationally and internationally to provide affordable treatments.

Key Sources

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Appendices

- 1) Bill C-91: An Act to amend the Patent Act.
- 2) Patent Act Patented Medicines Regulations, 1994
- 3) Patented Medicines Prices Review Board Compendium of Guidelines, Policies and Procedures.