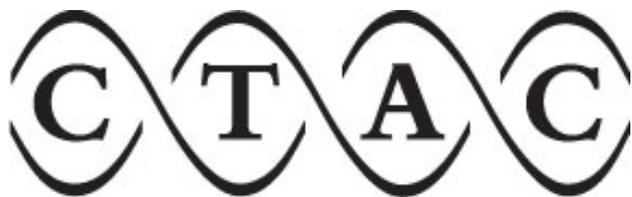


# **GENERIC DRUGS IN CANADA: *A POLICY PAPER***

**APRIL, 2007**



Canadian Treatment Action Council



Conseil canadien de surveillance  
et d'accès aux traitements

Prepared by:



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## EXECUTIVE SUMMARY

Many recent studies have found the price of generic drugs in Canada to be higher than the price of such drugs in comparator countries. This is especially significant to people living with HIV/AIDS as many of the drugs used to treat their condition will be genericized in the next few years. Ensuring the lowest possible price for these drugs will help ensure access for all who need them.

This Report provides an overview of background information related to the pharmaceutical market both globally and within Canada, followed by a summary of the regulatory mechanisms related to pharmaceutical review in Canada. Reimbursement of pharmaceuticals in general and generic drugs in particular, within Canada and in various international jurisdictions are discussed and models for possible emulation are highlighted. The Report then offers suggestions for possible mechanisms to reduce the price of generic drugs, discussing both the pros and cons of each option, and concludes with CTAC's recommendations.

### BACKGROUND

Generic pharmaceutical sales accounted for 17.7% of the total Canadian prescription drug market in 2003, totaling nearly \$3.0 billion of drugstore & hospital sales. Generic share of retail prescriptions was 44.0% equating to almost 173 million generic prescriptions.<sup>1</sup> While every Canadian province and territory encourages the use of generic drugs through a variety of regulatory mechanisms, each province varies in their share of spending on generic drugs. For instance, British Columbia has the highest share of generic prescriptions at 50.6% while Quebec has the lowest at 39.1%.

Generic drugs are less expensive than brand name drugs due to a number of factors: generic manufacturer's development costs are a fraction of those of the developer of a new drug; the time required to create a 'copy' is significantly less; regulatory hurdles are diminished for a generic manufacturer; and generic manufacturers have greater flexibility in pricing their products. Another difference between brand and generic drugs lies in the marketing of the products: generic manufacturers focus their marketing efforts on pharmacists and have been accused of providing inappropriate rebates to this group in the past.

Before an innovative medicine can be marketed in Canada it must pass through a complex regulatory process that involves a review of safety, effectiveness, and quality. This is followed by a review of cost effectiveness by the Common Drug Review, followed by a review by each of the individual provinces. Generic drug undergo an abbreviated submission at Health Canada, and then are available on the market.

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<sup>1</sup> Canadian Generic Pharmaceutical Association, Accessed March 5, 2007  
[http://www.canadiangenerics.ca/en/resource/market\\_trends.shtml](http://www.canadiangenerics.ca/en/resource/market_trends.shtml)

## CANADIAN ACCESS TO PRESCRIPTION DRUGS

The majority of Canadians pay for their prescription drugs through private and employer sponsored insurance. The public sector finances 46% of expenditures on prescription drugs. Approximately 10% of Canadians do not have access to either private or public insurance and must pay for their drugs out of pocket. The HIV/AIDS community is slightly different in that a greater proportion of people living with HIV/AIDS have access to public funding. It is estimated that 55% of Canadians living with HIV/AIDS make use of publicly funded drug programs.

Each Canadian province has differing rules and regulations surrounding the reimbursement of generic drugs. Ontario and Quebec's generic drug reimbursement require special mention as some studies have suggested that the policies of these two provinces have had a direct impact on the price of generic drugs in all of Canada.

In 1993, the Ontario government implemented a policy aimed at controlling the prices of generic drugs as a condition for listing them on its drug plan formulary (the list of products covered for reimbursement). That process was called the 75/90 rule and stipulated that the maximum price for the first interchangeable generic drug could only be 75% of the price of the brand name drug, and the maximum price for the second listed generic drug must be no more than 90% of the first generic drug. This policy has continued since then, in spite of numerous legal challenges by generic drug companies, although the percentages have changed; first to 60/90, then 70/90.<sup>2</sup> Ontario's recent Bill 102 amends the "70% rule" and now requires a first interchangeable generic drug be priced at no more than 50% of the brand name drug. This Regulation came into effect on March 1, 2007.

Unlike Ontario, Québec does not have a "70%" rule, however the government does insist on receiving the lowest or best available price in Canada. Many other provinces follow this policy, and therefore for the most part, prices of generic drugs in Canada are the same across the country.<sup>3</sup>

## INTERNATIONAL REGULATION

Most developed countries are grappling with the escalating importance of drugs to their health systems and many use some form of cost containment strategies to contain pharmaceutical expenditures. "The challenge of managing prescription drug costs, the approaches being tried, and the responses are surprisingly similar around the world."<sup>4</sup> The reimbursement systems in Australia, Finland,

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<sup>2</sup> Canada: Challenge to Pricing Policies for Generic Pharmaceuticals, *Apotex Inc v Minister of Health*, Court of Appeal for Ontario, 28 October 2004.

<sup>3</sup> Palmer D'Angelo Consulting, Inc. (2002). *Generic Drug Prices: A Canada US Comparison*. [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf)

<sup>4</sup>Currie, Gillian, Nielson, N. Models of Funding Prescription Drug Programs, Working Paper 2002-16. <http://scholar.google.com/scholar?hl=en&lr=&q=cache:Cxd->

Germany, New Zealand, Switzerland, the United Kingdom and the United States are described in the main body of the paper

## **CANADIAN GENERIC DRUG PRICES COMPARED**

There have been a number of studies published which have investigated the price of generic drugs in Canada versus other jurisdictions. The majority of these studies found that the prices of generic drugs in Canada are significantly higher than those found in comparator countries. Based on a review of the studies above, three main reasons for the relatively high price of generic drugs in Canada emerge: lack of competition (the generic drug landscape in Canada is dominated by two large players), government policies (generic drug reimbursement policies in Ontario and Quebec), and to a lesser degree, exchange rate fluctuations.

## **POSSIBLE MECHANISMS TO LOWER THE PRICE OF GENERIC DRUGS**

A number of possible policy options aimed at curbing the price of generic drugs in Canada are examined. The options under discussion include:

- I. Expansion of the Mandate of the PMPRB: The PMPRB regulation of brand pharmaceuticals has been considered responsible by some<sup>5</sup> as the reason Canada's patented drug prices are comparable with countries in the European Union. Expanding the mandate of the Board to regulate the prices of non-patented medicines could help moderate generic prices in Canada.
- II. Promotion of Competition in the Generic Manufacturing Sector: The Canadian generic drug market is dominated by two major players. Government incentives to "start up" generics companies may help increase the number of players and thus increase the amount of competition, which may allow for competitive market forces to take over and cause the price of generic drugs to decrease.
- III. Elimination of government 'Interference': Many researchers have cited provincial government pricing policies as one of the main reasons for inflated generic drug prices in Canada. If the Ontario government were to abolish its' 70/90 rule (now 50/90), manufacturers would no longer have this number as a (high) benchmark price. Furthermore, it has been argued that for the generic sector, price freezes have the effect of maintaining prices at an artificially high level: in a free market system, the prices of generic drugs tends to decrease with time.
- IV. Monosopist Model with International Competition: Based loosely on the New Zealand model, this concept involves the creation of a National Formulary with the government as a sole supplier for the country. The government purchaser will tender a contract to generic manufacturers (one

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[vFN0xs4J:www.ucalgary.ca/mg/research/media/2002\\_16.pdf+alternative%2Breimbursement%2Bdrug%2Bmodel](http://www.ucalgary.ca/mg/research/media/2002_16.pdf+alternative%2Breimbursement%2Bdrug%2Bmodel)

<sup>5</sup> Paris V, Docteur E, *Pharmaceutical Pricing nad Reimbursement Policies in Canada* OECD Health Working Papers, 22 December 2006.

company per product) and the lowest bidder receives the right to supply the entire Canadian market. The government can reserve the right to expand tenders to include international generics companies to ensure a strongly competitive market.

- V. Profit Controls for Generic Companies: Modeled after the Pharmaceutical Price Regulation Scheme in the UK, this model would involve control of generic manufacturers' *profitability*, as opposed to regulating *prices* of generic compounds. The underlying tenets of this model suggest that in order for a product to be reimbursed by the government, the manufacturer will agree to making a defined return on capital per year.
- VI. "International Reference Based Pricing for Generic Drugs": In this model, the Canadian (or provincial) government will introduce a scheme wherein generic drugs for certain conditions will be reimbursed only at a 'reference price'. This reference price will be set at the lowest price for a generic product that they can find – *from a select group of countries*. Products will still be produced in Canada, but the price paid for the product will be referenced at an international level.
- VII. Reduction of the 50% rule to a "Reasonable" level: It has been argued that the Ontario governments' "50% rule" is partially responsible for maintaining the prices of generic drugs at an artificially elevated level: what was supposed to be a price ceiling, has in effect had the opposite effect, and has provided generic manufacturers with a "price floor". An alternative to eliminating this type of government 'interference' altogether is to suggest a more realistic and reasonable percentage for generic prices. A formula that takes into account the real cost of research and production of the generic drug and incorporates a reasonable return on investment is suggested.
- VIII. Cross Border Importation of Generic Drugs from the US: As noted earlier, generic drugs in the US are significantly cheaper than they are in Canada. This model suggests allowing a 'reverse' cross border internet pharmacy scheme whereby Canadian citizens would purchase their generic drugs from approved American internet sites.
- IX. Bulk Buying of Generic Drugs: Given the fact that the provincial governments collectively are the largest purchasers of drugs in Canada, this gives them some clout where prices are concerned. This model suggests that the disparate governments unite to investigate the possibility of buying generic drugs in bulk in order to negotiate lower prices.

## CONCLUSION

It is apparent that some of the models suggested above may be more appropriate and feasible than others, such as expanding the mandate of the PMPRB, reducing the "50% rule", bulk buying, and cross border importation.

CTAC recommends that funding be provided in order to convene a focus group of experts and other appropriate individuals to discuss these options in more detail. Experts to be recruited include Federal/Provincial and Territorial (F/P/T) representatives, pharmaco-economic experts, health science industry members

(representatives from both brand and generic manufacturers), physicians, patients and pharmacists. These individuals would be charged with examining the issue and providing expanded recommendations to the government.

## INTRODUCTION

Many recent studies have found the price of generic drugs in Canada to be higher than the price of such drugs in comparator countries. This is especially significant to people living with HIV/AIDS as many of the drugs used to treat their condition will be genericized in the next few years. Ensuring the lowest possible price for these drugs will help ensure access for all who need them. At current prices, it is predicted that the generic industry will reap a significant windfall in the next year: "As more patents are expected to expire over the coming years, the generic industry is poised to benefit. In 2007 over \$1 billion in branded sales will likely be exposed to generic competition."<sup>6</sup> Furthermore a reduction in the prices of generic drugs will contribute to government cost containment strategies, freeing up health care spending to be allocated to other needed care and treatment: "Distorted generic drug pricing is important: this study shows that if Canadian drugs had been priced at median international levels, consumers and taxpayers could save \$810 million this year alone (2004)"<sup>7</sup>

The goal of this report is to inform and educate consumers and other stakeholders on the unique issues related to generic pricing in Canada, to provide context for the topic, to investigate why generic drugs in Canada are more expensive than in other developed countries, and finally to provide recommendations to reducing the price of generic drugs in Canada.

This Report provides an overview of background information related to the pharmaceutical market both globally and within Canada, followed by a summary of the regulatory mechanisms related to pharmaceutical review in Canada. Reimbursement of pharmaceuticals in general and generic drugs in particular, within Canada and in various international jurisdictions are discussed and models for possible emulation are highlighted. The Report then offers suggestions for possible mechanisms to reduce the price of generic drugs, discussing both the pros and cons of each option, followed by CTAC's recommendations.

## BACKGROUND

The Global pharmaceutical market reached \$565.9 billion (US) in 2005 according to IMS Health, a pharmaceutical data provider. At \$35 billion, generic sales accounted for 6% of that market. IMS forecasts that sales of generic drugs will increase by 20% by 2008 to reach over \$80 billion. The growth in sales is expected as many European markets are actively encouraging the use of less

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<sup>6</sup> CNW News Release, *First generic manufacturer to hit \$1 billion mark* March 21, 2007  
<http://www.newswire.ca/en/releases/archive/March2007/21/c4881.htm>

<sup>7</sup> Skinner, B. F. (2004). *Generic Drugopoly: Why Non-patented Prescription Drugs Cost More in Canada than in the United States and Europe*. Public Policy Sources. Report may be accessed at <http://www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&id=685>

expensive generics, coupled with the fact that a large number patents expire in the next year for numerous top-selling blockbuster drugs<sup>8</sup>.

**Table I: Global Pharmaceutical Sales, 1998 – 2005<sup>9</sup>**

<b>Global Sales</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
Total World Market (\$US billions)	\$298	\$331	\$356	\$390	\$427	\$497	\$559	\$602
% growth from previous year	7%	11%	11%	13%	9%	10%	8%	7%

The United States is the largest consumer of pharmaceutical products, with over 40% of the global market while Canada represents a relatively small portion (3.7%). According to the Canadian Institute of Health Information (CIHI) retail expenditure of drugs in 2005 reached \$24.8 billion in Canada (this includes prescribed and over-the-counter sales of brand and generic drugs).<sup>10</sup>

**Table II: Global Pharmaceutical Sales by Region, 2005**

<b>World Market</b>	<b>2005 Sales (US \$ Billions)</b>	<b>%Global Sales</b>
<b>Canada</b>	<b>\$21.1</b>	<b>3.7%</b>
North America (including Canada)	\$265.7	47.0%
Europe	\$169.5	30%
Japan	\$60.3	10.7%
Asia, Africa & Australia	\$46.4	8.2%
Latin America	\$24.0	4.2%
<b>Total</b>	<b>\$565.9</b>	<b>100%</b>

<sup>8</sup> IMS Health Web Site, *Generics Market Expected to Soar to \$80 Billion by 2008*, : [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_40183881\\_52651243,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_40183881_52651243,00.html)

<sup>9</sup> IMS Health Web Site, *Global Pharmaceutical Sales, 1998-2005* [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_77478579\\_77479643,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_77478579_77479643,00.html)

<sup>10</sup> Canadian Institutes of Health Information, *Drug Expenditure in Canada 1985-2005* [http://secure.cihi.ca/cihiweb/products/Drug\\_Expenditure\\_in\\_Canada\\_2006\\_final\\_web.pdf](http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_2006_final_web.pdf)

## GENERIC DRUGS IN CANADA

Generic pharmaceutical sales accounted for 17.7% of the total Canadian prescription drug market, totalling nearly \$3.0 billion of drugstore & hospital sales. Generic share of retail prescriptions was 44.0% equating to almost 173 million generic prescriptions.<sup>11</sup> According to IMS Health, generic drugs accounted for 50% of the growth in the number of prescriptions in 2003. While every Canadian province and territory encourages the use of generic drugs through a variety of regulatory mechanisms, each province varies in their share of spending on generic drugs. For instance, British Columbia has the highest share of generic prescriptions at 50.6% while Quebec has the lowest (39.1%).



(Map: Canadian Generic Pharmaceutical Association)

The generic drug market in Canada is dominated by two large players: Apotex and Novopharm/Teva. "Ontario-based Apotex became the first generic drug manufacturer to reach sales of more than \$1 billion in Canada. With drugstore and hospital purchases of \$1.1 billion, it is now the fourth largest pharmaceutical manufacturer in Canada behind brand-name companies Johnson & Johnson (\$1.121 billion) AstraZeneca (\$1.172 billion) and Pfizer (\$2.397 billion)."<sup>12</sup>

<sup>11</sup> Canadian Generic Pharmaceutical Association, Accessed March 5, 2007 [http://www.canadiangenerics.ca/en/resource/market\\_trends.shtml](http://www.canadiangenerics.ca/en/resource/market_trends.shtml)

<sup>12</sup> CNW News Release, *First generic manufacturer to hit \$1 billion mark* March 21, 2007 <http://www.newswire.ca/en/releases/archive/March2007/21/c4881.htm>

## **BRAND VERSUS GENERIC DRUGS: A COMPARISON**

“Generic drugs are less expensive [than brand name drugs] because generic manufacturers don’t have the investment costs of the developer of a new drug... Because those [generic drug] manufacturers don’t have the same development costs, they can sell their product at substantial discounts”<sup>13</sup> Generic drug manufacturers also do not have the same regulatory hurdles as brand drugs and have more flexibility in pricing their products. The following table provides an outline of the main reasons Canadian generic drug manufacturers are able to provide their medicines for a lower price than the patented counterpart.

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<sup>13</sup> FDA Centre for Drug Evaluation and Research  
[http://www.fda.gov/cder/consumerinfo/generics\\_q&a.htm](http://www.fda.gov/cder/consumerinfo/generics_q&a.htm)

**Table III: Brand versus Generic Drugs**

<b>Issue</b>	<b>Brand Medicine</b>	<b>Generic Medicine</b>
<b>Drug Development</b>		
Cost:	The average cost to develop a new medicine has been estimated at anywhere from <b>\$500 million to \$2 billion (US)</b> <sup>14</sup> .	The average cost to develop a generic copy is <b>\$1 million.</b> <sup>15</sup>
Time:	The medicine must undergo rigorous testing and several years of pre-clinical and clinical research. It takes anywhere from <b>10 to 15 years</b> to develop a single medicine. <sup>16</sup>	Approximately <b>2 to 3 years</b> is required to develop a chemically identical and biologically equivalent generic copy <sup>17</sup> .
<b>Regulatory</b>		
Drug Submission Requirements	To fulfill Health Canada's regulatory requirements, the company files a New Drug Submission – which contains many thousands of pages of clinical and chemistry data collected over several years.	The generic company presents an abbreviated submission to demonstrate that the copied drug is chemically identical and biologically equivalent.
Provincial Formulary Reimbursement	Lengthy formulary reimbursement process. Often leading to an unsuccessful outcome, or listing with many restrictions.	Generics file a simplified formulary submission and are virtually assured of receiving provincial reimbursement.
Prices	Prices are regulated by the Patented Medicines Prices Review Board (PMPRB).	Free market prices – generic drugs are not regulated in Canada.

<sup>14</sup> Adams CP, Brantner VV, *Estimating the cost of new drug development: is it really \$802 million?* Health Affairs, 25, no2(2006):420-428.

<sup>15</sup> "Prescription for high price" National Post, page A15, April 27, 2001

<sup>16</sup> Tufts University Center for the Study of Drug Development

<sup>17</sup> U.S. Congressional Budget Office *"How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry"*, July 1998.

Another area where brand drugs and generic drugs differ is in marketing and sales. Drugs are an atypical product in Canada: the final consumer of the product is not the one who makes the decision about brand and purchase. The patient's physician decides (ideally in discussion with the patient) which is the best drug to address the patient's condition. Federal government regulations in Canada do not allow advertising or marketing directly to the public, therefore, brand companies concentrate their marketing efforts on physicians. Pharmaceutical sales representatives must first gain access to a busy physician's time, and then they must convince the physician that their product is better than competitors based on their drug's unique qualities.

On the other hand, "Generic manufacturers focus their marketing efforts on pharmacists who make the decisions about which generic to dispense. In the US, generics are usually sold through wholesalers while in Canada they are sold directly from the generic manufacturers to retail pharmacies. Manufacturers who can supply a wide variety of products have a significant advantage as they can provide one stop shopping for retailers. Moreover, the generics may be providing additional value-added services to pharmacists in an effort to secure market share. Little is known about the nature and extent of the additional services and benefits that are offered by the generics firms to pharmacists in Canada."<sup>18</sup>

However, in Ontario, public hearings were held to consider recent changes to the statutes and Regulations governing the provincial drug plan. During those hearings it was revealed that generic manufacturers provided "rebates" of up to 60%<sup>19</sup> of the cost of generic drug products to encourage pharmacies to dispense their products. These "hidden rebates" accrued to pharmacies and not to consumers, clearly dispelling the myth that generic drug pricing in Ontario is designed to benefit patients and consumers.

The amount of money that these rebates may amount to across Canada is uncertain. However, in 2003, an article was published in *La Presse* that indicated that generic drug manufacturers had paid out rebates and bonuses to pharmacists in Québec and other provinces and therefore had circumvented the regulatory requirement in Quebec that the Quebec drug plan pay the "best available" price so that the best price could be in turn, passed on to consumers. This prompted a class action suit where the petitioner sought \$3.9 billion in damages, claiming that the generic drug manufacturers had caused both public and private insurance plans to pay excessive costs for generic drugs, excessive premiums and excessive contributions in the case of the public insurance plan.<sup>20</sup>

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<sup>18</sup> Palmer D'Angelo Consulting, Inc. (2002). *Generic Drug Prices: A Canada US Comparison*. <http://www.pdci.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf>

<sup>19</sup> Silversides, A *Pharmacies receiving massive rebates from generic drug-makers* CMAJ Aug 15 2006;175(4) <http://www.cmaj.ca/cgi/content/full/175/4/342>

<sup>20</sup> <http://www.gala-marketlaw.com/pdf/2006/Canada.pdf>

## REGULATION OF MEDICINES IN CANADA

The delivery of health care and the provision of health services in Canada falls under the jurisdiction of the provincial governments. It is the *Canada Health Act* that “establishes the criteria and conditions related to insured health care services - the national standards - that the provinces and territories must meet in order to receive the full federal cash transfer contribution under the transfer mechanism, that is, the Canada Health and Social Transfer (CHST).”<sup>21</sup> Canadians spent \$142 billion on health care in 2005, or \$4,411 per capita<sup>22</sup>.

“In this decentralized health system, provinces and territories are responsible for the management, organisation and delivery of hospital and physician services and may offer supplemental coverage for other medical goods and services, including prescription drugs furnished outside of the hospital, for all or part of their residents.”<sup>23</sup> Prescription drugs however, are not considered ‘medically necessary’ when delivered outside of the hospital and a slim majority of Canadians rely on private and employer sponsored insurance to pay for drugs. However, the public prescription drug programs pay for a larger market share of drugs in Canada.

Before a drug can be prescribed to patients however, it must first pass through a complex regulatory process.

### ***Health Canada***<sup>24</sup>

In the case of a brand drug, once the drug has completed a series of pre-clinical and clinical trials, a New Drug Submission is submitted to Health Canada. There are two review bodies within Health Canada; the Therapeutic Products Directorate, which reviews chemical entities and compounds, and the Biologic and Genetic Therapeutics Directorate which reviews biologically based therapies, compounds, vaccines and stem cell therapies. Depending on what type of compound is being reviewed, the manufacturer submits evidence (preclinical, clinical, chemistry & manufacturing data) from clinical trials to one of these two bodies. The evidence must prove that their compound is safe, effective, of high quality, and that the benefit(s) of the drug outweighs any possible side effects that may occur. If scientists at Health Canada deem that the drug meets the requirements, a Notice of Compliance is given to the drug and the manufacturer can begin selling the drug on the Canadian market.

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<sup>21</sup> Health Canada web site, accessed March 5, 2007 [http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2002/2002\\_care-soinsbk4\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2002/2002_care-soinsbk4_e.html)

<sup>22</sup> Canadian Institute for Health Information, Health Care in Canada 2006, [http://secure.cihi.ca/cihiweb/products/hcic2006\\_e.pdf](http://secure.cihi.ca/cihiweb/products/hcic2006_e.pdf)

<sup>23</sup> Paris V, Docteur E, *Pharmaceutical Pricing nad Reimbursement Policies in Canada* OECD Health Working Papers, 22 December 2006

<sup>24</sup> Health Canada, *Overview of the Canadian Federal Drug Review Process*, [http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/overview-apercu\\_drug-med\\_rev\\_pro\\_03\\_07\\_e.html#7](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/overview-apercu_drug-med_rev_pro_03_07_e.html#7)

Occasionally, a product is given a Notice of Compliance with Conditions (NOC/C). An NOC/c is authorization to market a drug (i.e. a Notice of Compliance (NOC)), with the condition that the sponsor undertake additional studies to verify the clinical benefit.<sup>25</sup> An NOC/c is only given in specific circumstances such as:

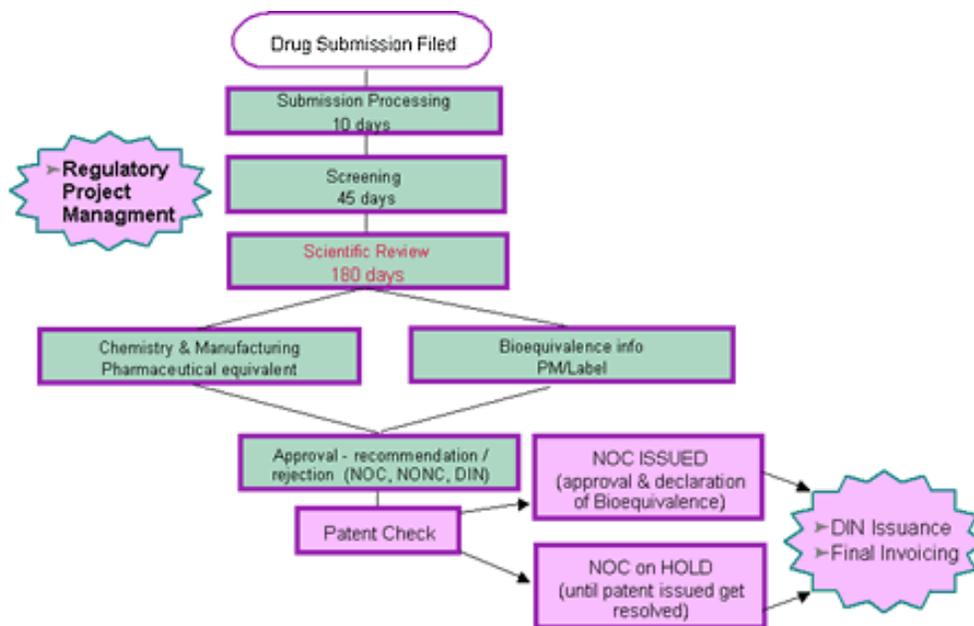
- If there is no alternative therapy on the market, or
- Where the product represents a significant improvement over existing therapies on the market.

Manufacturers of brand medicines must also submit their suggested price for the drug to the Patented Medicines Prices Review Board (PMPRB) which will be discussed in a following section.

Generic manufacturers must file an Abbreviated New Drug Submission (ANDS), and the manufacturer is obligated to establish bioequivalence of their drug to the 'Canadian Reference Product' (CRP). If the manufacturer can establish that their product follows the same route of administration and the same conditions for use as the CRP, while ensuring safety, efficacy and quality, the generic drug is given clearance to be marketed in Canada.

The process for reviewing a generic drug submission is as follows:

### Review of Generic New Drugs<sup>26</sup>



<sup>25</sup> Health Canada, Drugs and Health Products, Notice of Compliance with Conditions, [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index_e.html)

<sup>26</sup> Health Canada web site [http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/overview-apercu\\_drug-med\\_rev\\_pro\\_03\\_07\\_e.html#7](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/overview-apercu_drug-med_rev_pro_03_07_e.html#7)

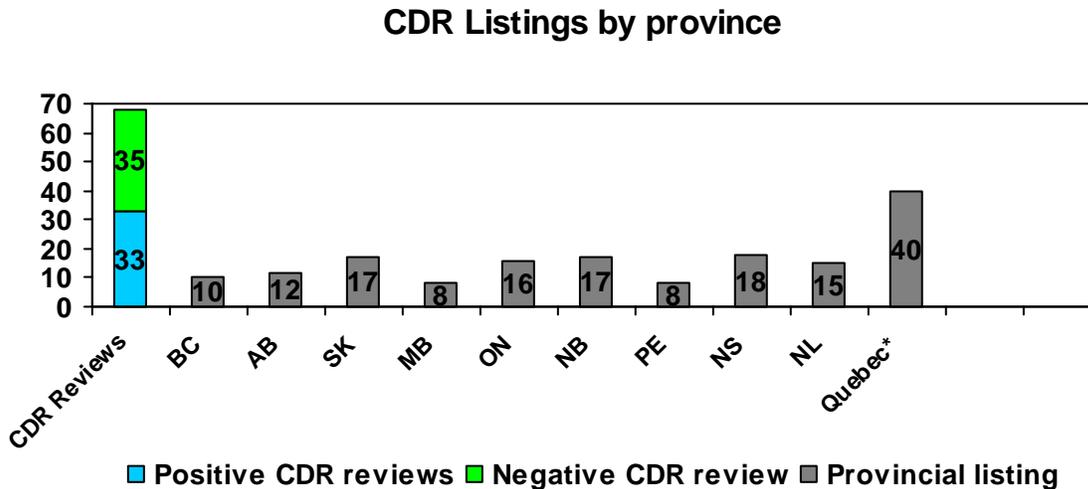
## Common Drug Review

If brand manufacturers wish to have their drugs considered for reimbursement by participating provincial and federal government plans, they must submit their drug for review by the Common Drug Review (CDR). The CDR began reviewing drugs in 2003, and it “conducts objective, rigorous reviews of the clinical and cost effectiveness of new drugs, and provides formulary listing recommendations to the publicly funded drug plans in Canada (except Québec).”<sup>27</sup>

While Health Canada reviews drugs to assess their safety, efficacy, and quality, the CDR reviews the pharmacoeconomic profile of the drug. This review is an attempt to determine whether the drug will provide value for money, and determine how it compares to alternatives currently on the market. The CDR provides a recommendation for all participating Federal, Provincial and Territorial drug plans.

It should be noted that Quebec opted out of the CDR, but all other provinces are members. Provincial uptake of CDR decisions however remains extremely inconsistent and varies widely between provinces:

**Table IV: CDR Listings by Province, to March 2007**



<sup>27</sup> CADTH/CDR web site: <http://www.cadth.ca/index.php/en/cdr/cdr-overview>

## ***Patented Medicines Prices Review Board***

The prices of brand name drugs are regulated through the Patented Medicines Prices Review Board (PMPRB). “As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organizations such as Health Canada...and public drug plans...”<sup>28</sup> The PMPRB’s role is to ensure that the prices charged by manufacturers for patented medicines is not ‘excessive’. They do so by:

- Limiting the price of most new patented drugs so that the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease;
- Limiting the price of breakthrough drugs to the median of the prices for the same drugs charged in other specified industrialized countries that are set out in the Patented Medicines Regulations (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.);
- Ensuring that existing patented drug prices are not increased by more than the Consumer Price Index (CPI);
- Ensuring that the Canadian prices of patented medicines are never the highest in the world.

The prices of generic drugs are not regulated by the PMPRB or any other Canadian body.

## **CANADIAN ACCESS TO PRESCRIPTION DRUGS**

Many payers are involved in financing prescribed drugs in Canada. “In the public sector, these payers include provincial/territorial/financial drug subsidy programs and social security funds. In the private sector, they include private insurers and households.”<sup>29</sup> According to a study by Health Canada, 10% of Canadians do not have access to any form of insurance from either the public or the private sector and must therefore pay for their drug costs out of pocket<sup>30</sup>. As can be seen in Table V, the public sector finances an average of 46% of drug expenditures in Canada.

The HIV/AIDS community is slightly different in that a greater proportion of people living with HIV/AIDS have access to public funding. It is estimated that 55% of Canadians living with HIV/AIDS make use of publicly funded drug programs.

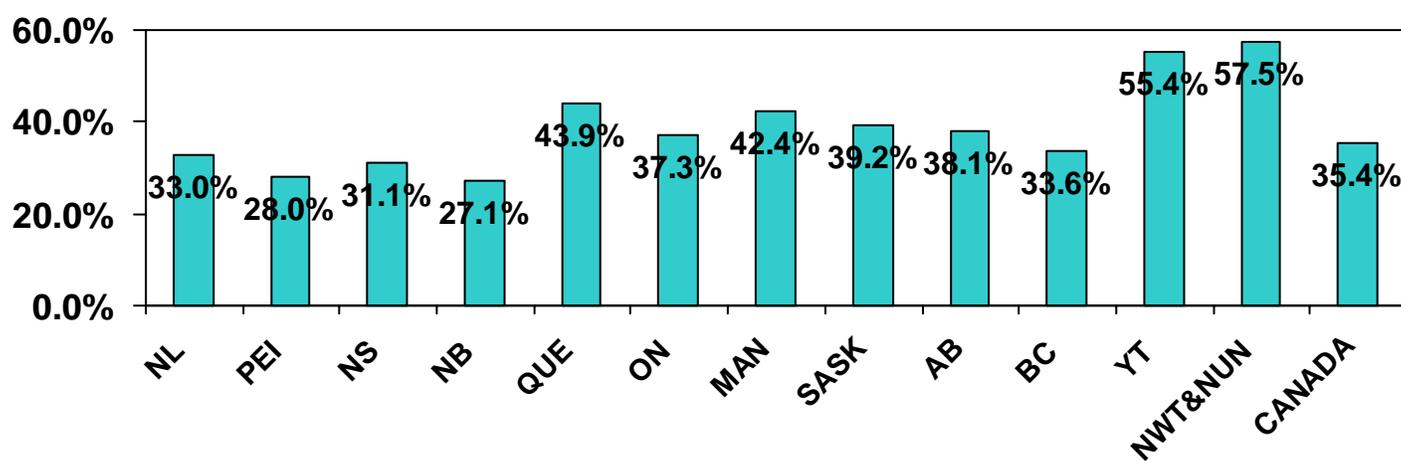
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<sup>28</sup> PMPRB web site, accessed March 5, 2007 <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#2>

<sup>29</sup> Canadian Institutes of Health Information, *Drug Expenditure in Canada 1985-2005* [http://secure.cihi.ca/cihiweb/products/Drug\\_Expenditure\\_in\\_Canada\\_2006\\_final\\_web.pdf](http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_2006_final_web.pdf)

<sup>30</sup> Applied Management et. al. *Canadians’ Access to Insurance for Prescription Medicines* Health Canada, March 2000 [http://www.hc-sc.gc.ca/hcs-sss/alt\\_formats/hpb-dgps/pdf/pubs/2000-htf-fass-acces-med/2000-htf-fass-acces-med\\_e.pdf](http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2000-htf-fass-acces-med/2000-htf-fass-acces-med_e.pdf)

**Table V: Publicly Financed Drug Expenditure as a Percentage of Total Drug Expenditure, by Province & Territory, 2005<sup>31</sup>**



From an international perspective, Canada has the third highest level of total drug expenditure per capita after the United States and France. In contrast, the public sector funded 38.1% of total drug expenditure in Canada in 2003. This was the third lowest share of the sixteen comparator countries after only the United States (21.2%) and Mexico (11.3%).<sup>32</sup> Within Canada, total drug expenditure per capita is forecast to have ranged from \$652 in British Columbia to \$837 in Ontario. The variation in spending between provinces has been found not to be related to price, but rather by differences in the volume of drugs purchased, and the selection of drugs dispensed: “Removing estimated dispensing fees from all provinces, based on average fees paid by provincial drug plans, reduces drug price variation across Canada to only 4%... In general, observed differences in per capita expenditures stem from multiple cost-drivers, the most significant being the volume of drugs purchased and the type of products selected.”<sup>33</sup>

Each province has its own set of rules and regulations for the reimbursement of drugs for its residents. As a result, the proportion of prescribed drugs financed by the public sector in 2005 varied across the provinces and is forecast to range, from a low of 27.1% in New Brunswick to a high of 57.5% in Nunavut and the North West Territories. One province ensures that all residents have some form of drug coverage (Quebec), while others cover only a fraction of their population (i.e. most Maritime provinces). While all provinces attempt to ensure the

<sup>31</sup> Canadian Institutes of Health Information, *Drug Expenditure in Canada 1985-2005*  
[http://secure.cihi.ca/cihiweb/products/Drug\\_Expenditure\\_in\\_Canada\\_2006\\_final\\_web.pdf](http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_2006_final_web.pdf)

<sup>32</sup> Canadian Institutes of Health Information, *Drug Expenditure in Canada 1985-2005*  
[http://secure.cihi.ca/cihiweb/products/Drug\\_Expenditure\\_in\\_Canada\\_2006\\_final\\_web.pdf](http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_2006_final_web.pdf)

<sup>33</sup> Morgan S, *Sources of variation in provincial drug spending* Canadian Medical Association Journal, Feb 3, 2004;170(3)

continued use of generic drug products where applicable (through mandatory generic substitution policies for example), there is variation in how this is accomplished in each province. The following section describes the policies related to generic drugs in a selection of Canadian provinces.

## **GENERIC DRUG REIMBURSEMENT POLICIES IN SELECT CANADIAN PROVINCES**

### ***Ontario***

In 1993, the Ontario government implemented a policy aimed at controlling the prices of generic drugs as a condition for listing them on its drug plan formulary (the list of products covered for reimbursement). That process was called the 75/90 rule and stipulated that the maximum price for the first interchangeable generic drug could only be 75% of the price of the brand name drug, and the maximum price for the second listed generic drug must be no more than 90% of the first generic drug. This policy has continued since then, in spite of numerous legal challenges by generic drug companies, although the percentages have changed; first to 60/90, then 70/90.<sup>34</sup>

It should be noted that while this policy has had the unintended consequence of allowing generic drug manufacturers to maintain artificially high prices for their products across the country, the generic manufacturers have fought against this legislation. One manufacturer took the Ontario government to court challenging that the legislation, as it then read, only authorized the Minister to make regulations that set the “best available price” for any particular drug using a method prescribed in the legislation. The Divisional Court agreed with the manufacturer that the legislation did not allow the Minister to use the price of other drugs as a factor in determining the “best available price”. Following the Divisional Court decision, the legislation was amended in 1996 by removing the reference to “best available price,” substituting the “drug benefit price,” allowing the Minister to consider the drug benefit price of other drug products in determining the drug benefit price of a particular drug product.<sup>35</sup>

In June 2006 *Bill 102; The Transparent Drug System for Patients Act* received third and final reading in the Ontario legislature. The Bill amends the “70% rule” and now requires a first interchangeable generic drug be priced at no more than 50% of the brand name drug. This Regulation came into effect on March 1, 2007.

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<sup>34</sup> Canada: Challenge to Pricing Policies for Generic Pharmaceuticals, *Apotex Inc v Minister of Health*, Court of Appeal for Ontario, 28 October 2004.

<sup>35</sup> Best, R. *Canada: Challenges to Pricing Policies for Generic Pharmaceuticals* Pharmablawg a legal weblog <http://www.pharmablawg.com/pharmablawgposts/canada-challenge-to-pricing-policies-for-generic-pharmaceuticals.html>

When the change to the “70%” rule was first announced, the generic drug manufacturers indicated that they felt the rule was unfair as they would not be able to generate a profit for certain drugs if they were priced at the 50% level. In fact, they threatened “to cut the supply of up to 150 medications to Ontario’s drug benefit plan – including antidepressants and a drug to control heart arrhythmia.”<sup>36</sup> In face of this threat, the Drug System Secretariat revisited the issue, and began negotiations with the generics drug industry in the hopes of resolving the dispute.

In response to this threat, the Executive Officer sent a notice describing certain changes including “We have been in discussion with the generic manufacturers concerning the pricing of selected generic products. In response to concerns raised among stakeholders, I am proposing to negotiate prices for these specific single source generic drugs in limited exceptions to the 50% price rule; this would also include first-to-market generic products.”<sup>37</sup>

In December 2006, the Executive Officer provided a further update to the progress of Bill 102 and announced changes to the regulations which indicated that exceptions to the new 50% generic price rule would be possible: “Regulations...Create exceptions to the 50% generic price rule where the product is the only generic product available on the market or where the product is the first generic product on the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary) and allow the Executive Officer to negotiate agreements for any drug benefit price lower than the original product price”.<sup>38 39</sup>

## **Québec**

Unlike Ontario, Québec does not have a “70%” rule, however the government does insist on receiving the lowest or best available price in Canada. Many other provinces follow this policy, and therefore for the most part, prices of generic drugs in Canada are the same across the country.<sup>40</sup>

Québec is unique in that 42% of national pharmaceutical research investment takes place here and a large number of Canadian pharmaceutical companies have their head offices in this province. The Québec government therefore is hesitant to demand too many concessions from an industry that provides significant economic benefit to the province. “Instead of negotiating prices directly, the Québec government requires that manufacturers charge it no more

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<sup>36</sup> Gandhi, U *Ontario battling drug firms* Globe & Mail, October 31, 2006.

<sup>37</sup> Spaford R, *Notice from the Executive Officer*, Ministry of Health and Long Term Care, [http://www.health.gov.on.ca/english/providers/program/drugs/formulary/bul\\_exec\\_110106.pdf](http://www.health.gov.on.ca/english/providers/program/drugs/formulary/bul_exec_110106.pdf)

<sup>38</sup> Ontario Ministry of Health and Long Term Care, accessed February 28 2007

[http://www.health.gov.on.ca/english/public/legislation/drugs/drugsact\\_bulletin4.html](http://www.health.gov.on.ca/english/public/legislation/drugs/drugsact_bulletin4.html)

<sup>39</sup> Manulife Benefits Bulletin,

[http://groupbenefits.manulife.com/canada/GB\\_v2.nsf/LookupFiles/BenefitBulletinsBenefitsBulletinNov2006/\\$File/BenefitsBulletin\\_nov2006.pdf](http://groupbenefits.manulife.com/canada/GB_v2.nsf/LookupFiles/BenefitBulletinsBenefitsBulletinNov2006/$File/BenefitsBulletin_nov2006.pdf)

<sup>40</sup> Palmer D’Angelo Consulting, Inc. (2002). *Generic Drug Prices: A Canada US Comparison*. [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf)

than the best available price in the rest of Canada. One unintended impact of this political compromise is that it appears to have created a "price floor" for smaller provinces because manufacturers must grant Québec concessions given to any other province. In Saskatchewan, for example, where the government tenders standing-offer contracts for multisource products, the prices of such drugs increased greatly following the 1993 implementation of Québec's pricing policy"<sup>41</sup>

Residents of Québec in general spend more on prescription drugs than other Canadians: "Residents of Quebec... used more prescription drugs, used a more expensive mix of products and paid more per unit purchased than did residents of the other provinces."<sup>42</sup>

### **British Columbia**

British Columbia uses reference based pricing (RBP) which encourages competition and low pricing from generic manufacturers. The province does not place pricing restrictions on the generic drug manufacturers; instead they pay the actual acquisition cost for the drug set by the generic manufacturer (plus a 7% markup for pharmacy profit). The lowest cost generic product becomes the reference drug – or the drug that will receive the full benefit. Other generics receive partial benefit. When another manufacturer lowers the price of their drug, this new drug then becomes the reference drug. According to BC Pharmacare, the full benefit drug changes on a very regular basis. Pharmacies are informed of the change (and are given 30 days' notice through a newsletter to get rid of their stock of the previous full benefit drug) and the new drug then receives the full benefit. Pharmacies who have overstocked on the previous reference drug will occasionally just continue to dispense the product, passing the extra cost along to the patient. Patients are therefore doubly burdened as they pay more for their drugs and face constant switching between brands.<sup>43</sup>

### **Saskatchewan<sup>44</sup>**

Saskatchewan does not have particular regulations related to the pricing of generic drugs. "All the generics seem to match in price."<sup>45</sup> The only price difference tends to be in package size. When a brand drug is genericized, pharmacists have 60 days to clear their stock of the brand-name drug and thereafter the Saskatchewan drug plan will only reimburse for the cost of the

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<sup>41</sup> Morgan SG, Barer ML, Agnew JD *Whither Seniors' Pharmacare: Lessons from (and for) Canada* Health Affairs, 22, no. 3(2003):49-59

<sup>42</sup> Morgan S, *Sources of variation in provincial drug spending* Canadian Medical Association Journal, Feb 3, 2004;170(3)

<sup>43</sup> Personal Communication, BC Pharmacare representative, February 28, 2007

<sup>44</sup> All Saskatchewan information from the web site <http://formulary.drugplan.health.gov.sk.ca/>

<sup>45</sup> Personal Communication, Drug Plan and Extended Benefits Branch, Formulary section, March 1, 2007.

generic drug. Any drug in a Low Cost Alternative interchangeable group can be used to fill a prescription. The drug cost component in the approved prescription price is the actual acquisition cost of the drug up to the lowest price listed in the formulary within that interchangeable group.

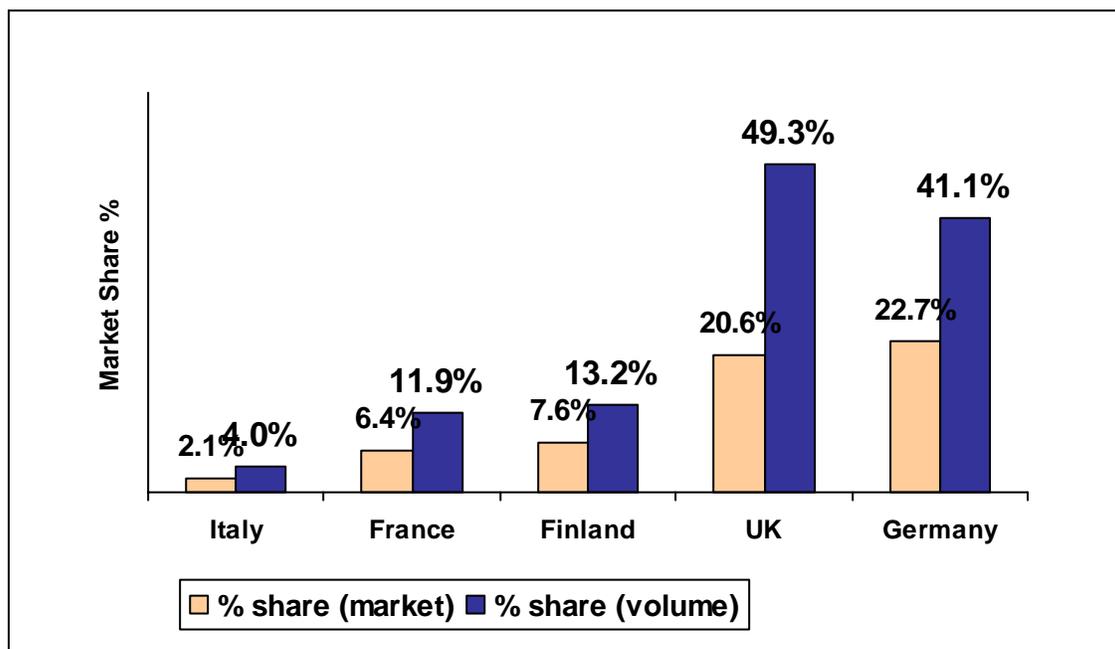
Saskatchewan also uses “Standing offer Contract” which is described on their web site as: The Drug Plan tenders the drugs in certain interchangeable groups to obtain the lowest possible price. An accepted tender, called SOC, requires the manufacturer to guarantee delivery of the specific drug to pharmacies through approved distributors at the contracted price. In return, the manufacturer's product will be used almost exclusively. Only the accepted tendered drug can be used to fill a prescription in an SOC interchangeable group. If a prescription is ordered as "no substitution" for any brand other than the SOC brand listed, the Drug Plan will cover the actual acquisition cost up to the listed SOC unit price. The difference in acquisition cost between the brand dispensed and the cost covered by the Drug Plan is the responsibility of the patient.

Finally, Saskatchewan uses a “Maximum Allowable Cost” for the Proton Pump Inhibitor (PPI) therapeutic class of drugs. As of March 1, 2007 the drug plan will reimburse up to a maximum of \$1.51 per pill. If the patient needs a more expensive drug, they will be required to pay the difference. If the patient needs a less expensive drug, the pharmacist will only bill the drug plan the actual acquisition cost.

## **INTERNATIONAL REGULATION OF PHARMACEUTICAL PRODUCTS: SELECT COUNTRIES**

The following section will outline the pricing, reimbursement and regulatory environment for pharmaceutical products in general, and generic drugs in particular in select international markets.

**Table VI: Generic Market Shares in Select European Countries, 2004**



Most developed countries are grappling with the escalating importance of drugs to their health systems and many use some form of cost containment strategies to contain pharmaceutical expenditures. It does not appear that any country in the world has completely open access to all medicines available and patients are invariably responsible for some portion of the drug cost. “The challenge of managing prescription drug costs, the approaches being tried, and the responses are surprisingly similar around the world.”<sup>46</sup>

Despite the fact that studies have shown that increased spending on drugs and medicines improve life expectancy and improved health outcomes<sup>47</sup>, payers continue to focus on drug spending as a cost driver. A common theme among jurisdictions is an increasing emphasis on the ‘fourth hurdle’ of drug evaluation - namely health economic review or cost effectiveness analysis. This remains a controversial concept as patients who require the life-saving or life-altering medicines feel these medicines should be reimbursed regardless of the cost, and according to some, cut off points appear to be somewhat arbitrarily determined: “Although there has been general agreement on the necessity for economic evaluation and much debate regarding methods, no consensus has been

<sup>46</sup>Currie, Gillian, Nielson, N. Models of Funding Prescription Drug Programs, Working Paper 2002-16. [http://scholar.google.com/scholar?hl=en&lr=&q=cache:Cxd-vFNoxs4J:www.ucalgary.ca/mg/research/media/2002\\_16.pdf+alternative%2Breimbursement%2Bdrug%2Bmodel](http://scholar.google.com/scholar?hl=en&lr=&q=cache:Cxd-vFNoxs4J:www.ucalgary.ca/mg/research/media/2002_16.pdf+alternative%2Breimbursement%2Bdrug%2Bmodel)

<sup>47</sup> Cremieux, PY, Meilleur, MC, et al *Private and Public Pharmaceutical Spending as Determinants of Health Outcomes in Canada*, Health Econ. 14:107-116. 2005

reached on how to perform economic analyses and what should or should not be included.”<sup>48</sup>

The following section describes the reimbursement systems in Australia, Finland, Germany, New Zealand, Switzerland, the United Kingdom and the United States.

### **Australia**

Once a drug has been approved for use in Australia, the manufacturer must apply to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the Pharmaceutical Benefits Scheme (PBS). PBAC’s recommendations are based on four criteria: safety, efficacy, cost effectiveness and community need. If the drug is approved for PBS listing by PBAC it is then sent to the Pharmaceutical Benefits Pricing Authority, which recommends a price.

A final decision on PBS listing price rests with the Minister of Health. The prices of all PBS listed products are reviewed annually. Department of Finance and Administration approval is required for products that are expected to cost the government more than \$5 million (Australian dollars) per year. If drugs are expected to cost more than A\$10 million per year, it is a federal requirement that approval for listing be obtained by the Cabinet, in addition to the Minister of Health.

The final cost to the consumer of a PBS listed medicine is made up of three elements: (i) the agreed price negotiated between the Australian government and the manufacturer; (ii) a controlled mark-up applied by wholesalers and pharmacists; and (iii) a pharmacist dispensing fee determined by independent tribunal. Companies are permitted to price above the PBS benchmark, but patients will likely pay a premium in addition to the normal co-pay.

Generic drugs are subject to the same pricing regulation as innovative drugs.

Australia will reimburse patients only for those drugs listed on the PBS, and for which a reimbursement price has been agreed. (If the government does not reimburse the drug, the company is under no restrictions regarding the price they attach to the drug and can change prices freely.) All patients are required to pay a deductible to the pharmacist for each drug they purchase. If the cost of the medicine is lower than the deductible, the patient pays the actual cost.

Generic substitution has been aggressively promoted since legislation was introduced in 1994. Pharmacists however, are allowed to substitute products on the PBS only when the patient agrees to the substitution, the brands are identified as being interchangeable, the prescriber has not specifically stated that a substitution should not occur and the substitution is permitted under State

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<sup>48</sup> Drummond MF, *The use of health economic information by reimbursement authorities* Rheumatology 2003;42(Suppl.3):iii60-iii63.

legislation. To further increase the use of generic drugs, as of November 2002, the computer-prescribing programs used by physicians automatically suggest a generic product, unless the physician specifies a brand name product.

### ***Finland***

In Finland, new pharmaceutical drugs enter the market either after receiving approval from the National Agency for Medicines or through the European market authorization system. The Pharmaceuticals Pricing Board establishes pricing, regulates the prices of drugs reimbursable by the NHI, and places no restrictions on pricing for drugs which have a marketing license. The Pharmaceuticals Pricing Board also receives applications for wholesale price increases for drugs which are reimbursable. Pharmaceutical drugs may only be sold by pharmacies, and most drugs which receive sales permission are licensed as reimbursable. The location and number of pharmacies in Finland are controlled, are privately owned, and require a license from the National Agency for Medicines.

Generic prescription use is small, and new changes allow the name of the generic drug to be written on the prescription instead of the brand name. The use of new expensive drugs has influenced rising pharmaceutical costs in Finland; which increased by about 10% from 1990 through 1998.

During the past ten years, a number of procedures have been implemented to contain pharmaceutical costs, including (a) a compulsory stockpiling system to maintain adequate pharmaceutical supplies during emergency conditions; (b) the therapeutic cost-effectiveness and value of new drugs must be demonstrated before they are eligible for a 75 – 100% reimbursement; (c) the formula for deciding pharmacy profit margins was made more regressive and simplified; (d) the value-added tax on drugs was lowered to 8% (from 12% previously); and (e) a nationwide program was initiated to make doctors more aware of effectiveness of their prescribing practices.<sup>49</sup>

After introducing the above procedures, growth in pharmaceutical spending slowed during 1998. Drug expenditures and reimbursement costs began increasing at a rate of over 8% in 1999; and although there was a short term impact of containing prescription drug costs, new measures are being considered for the future.

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<sup>49</sup> World Health Organization Regional Office for Europe (2007). *Finland*. [http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020425\\_4](http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020425_4)

## Germany

Germany maintains one of the most significant pharmaceutical industries among developed countries, and the German pharmaceutical industry has more than tripled import and export turnover since 1992.<sup>50</sup>

The 1976 Pharmaceutical Act mandates the licensing of new drugs, provides guidelines by the Ministry of Health, and is the most regulated area of medicine within Germany. The Paul Ehrlich Institute is responsible for the admission of human pharmaceuticals in the market, and the Federal Institute for Pharmaceuticals and Medical Devices is responsible for all other drugs. Licenses are given for a variety of doses and applications forms of drugs, which yield over 40,000 items on the drug market. Germany's Red List registry maintains over 9000 preparations, and the criteria for licensing pharmaceuticals are efficacy and scientifically proven safety. To fulfill the efficacy criteria, only a marginal beneficial effect from a small sample needs to be demonstrated, and cost-effectiveness is not considered. Licensing is limited to five years, with extensions available after this time period.

Pharmaceutical drugs may be dispensed by public and institutional pharmacies, and hospitals, or by drug stores and supermarkets if they are not labelled pharmacy only.

Pharmaceutical price regulation differs between the ambulatory sector and the inpatient sector. Hospitals may negotiate prices with manufacturers or wholesalers, and distribution prices and chains are more heavily regulated. For prescription-only drugs, pharmacists are paid a flat rate payment of €8.10 plus a fixed margin of 3%. For over the counter (OTC) drugs, pharmacies may individually choose prices.

Germany does maintain a positive list of SHI reimbursable pharmaceuticals, and until 2003, market entry for most pharmaceutical drugs included SHI coverage. Exceptions to this coverage included drugs which were determined inefficient by the Social Code Book, drugs for trivial diseases, lifestyle drugs, and OTC drugs which are not reimbursable by sickness funds (except for children under 12 years of age).

As a means of indirectly controlling cost, reimbursement of pharmaceuticals has been further regulated by reference prices since 1989. In Germany, reference prices refer to sickness funds that only reimburse pharmacies to a predetermined ceiling and patients pay the difference between the market price and the reference price. Tighter regulations were implemented through the Act to Strengthen Solidarity, which prohibited the setting of reference prices which were

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<sup>50</sup> WHO Regional Office for Europe, European Observatory on Health Care Systems (2000). *Health Care Systems in Transition: Germany*. Report may be accessed at <http://www.euro.who.int/document/e68952.pdf>

higher than the highest price in the lowest third of the market. Reference based pricing has been determined to be effective in cost containment. Since 2000, spending caps were eliminated, and replaced by negotiated cost control targets and prescriptions.

### ***New Zealand***

Once a drug has been approved for use in New Zealand, the Pharmacology and Therapeutics Advisory Committee (PTAC) makes recommendations regarding reimbursement of a drug. Critics have argued that PTAC operates on a fairly informal and non-transparent manner, which has led to a “growing concern that, in effect, PTAC has simply become part of price bargaining.”<sup>51</sup>

Pharmaceutical reimbursement is unique in New Zealand as the government chooses to reimburse only *one* drug for a relatively wide range of conditions. Using sole source tenders to keep down the price of a drug is effective, as manufacturers are expected to agree to a lower price in return for the ability to supply the entire NZ market. Further, the budget for funding pharmaceuticals is capped. For example, the ability to grant “special authority” for a drug is limited by the budget cap rather than by clinical considerations. Thus access to drugs is varied through the year in order to keep to budget. New Zealand thus has one of the most restrictive levels of access in the five jurisdictions under review.

However, the entire population of New Zealand is covered by their drug subsidy program. In the past the co-payment system was based on income, with lower income individuals paying \$3.00 per 3 month prescription and those with higher incomes paying up to \$15 per 3 month prescription. This has recently changed however, and now all residents pay the \$3.00 co-payment.

New Zealand also uses reference based pricing: a price is set for a whole class of drugs by reference to the cheapest drug in the class, even if the class is so broad that the drugs within it are not substitutable for each other for clinical purposes. Reference pricing has a particularly strong impact because the price of the ‘winning’ medicine is applied to the entire therapeutic group without differentiation for therapeutic effect.

### **Switzerland**

In Switzerland, the Intercantonal Office for the Control of Medicines is the authority responsible for registering pharmaceutical drugs. Pharmaceuticals are separated into several legal categories; and over the counter drugs are separated into three distinct categories, including drugs which can be sold in pharmacies, drugs which may only sold in pharmacies, and drugs which cannot

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<sup>51</sup> Sundakov, A and V, *New Zealand Pharmaceutical Policies*, Castalia Strategic Advisors, August 2005

be sold anywhere. Any pharmaceutical company that intends to introduce a drug to the market must complete and pay for the registration procedure.

Maximum prices are set for pharmaceutical products for which the compulsory health insurance system will pay. The Federal Office of Social Insurance determines the pharmaceuticals which are placed on this list. Sanphar is an association representing the Swiss pharmaceutical companies, and determines the price structure and pricing code for pharmaceutical retail prices, wholesale prices, and selling prices.

The thirteen cantons determine which doctors have the authority to sell pharmaceuticals, and there are no restrictions on the number of dispensing doctors in the cantons. The majority of medicines (62%) are sold through pharmacies, with doctors dispensing approximately 20%, hospitals approximately 12%, and drugstores approximately 6%. Pharmaceuticals represent approximately 11.6% of total health expenditures in Switzerland, and 33% of all medicines are produced and sold within the country. Over 90% of the pharmaceutical drugs manufactured in Switzerland are exported.

Pharmaceutical expenditures have risen steeply recently, which is partly due to financial incentives to prescribe expensive drugs. Revisions of the health insurance law are being considered to promote the sale of generic drugs. To ensure this does not negatively affect pharmacists' income, payment for services rendered will replace the pharmacy margin.

Consideration has been recently given to developing a federal law on pharmaceuticals which will replace the intercantonal pharmaceutical agreement. The intent of the new law would be to remove areas of responsibility which currently overlap among federal, intercantonal, and cantonal regulations.<sup>52</sup>

### ***United Kingdom***

Control of pharmaceutical budgets takes place at the regional level in the UK: local Primary Care Trusts of the National Health Service manage and subsidize pharmaceuticals for all residents. The National Institute for Health and Clinical Excellence (NICE) was established in 1999 to address the variations in health care across regions that resulted from this arrangement. Primary Care Trusts are now obligated to fund all medical technologies reviewed and recommended by NICE in their guidance documents. NICE only reviews technologies likely to have major health implications, budgetary impact, or controversy over effectiveness.<sup>53</sup>

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<sup>52</sup> World Health Organization Regional Office for Europe. (2000). *Health Care Systems in Transition: Switzerland*. <http://www.euro.who.int/document/e68670.pdf>

<sup>53</sup> Morgan Steven G, et. al. *Centralized Drug Review Processes in Australia, Canada, New Zealand and the United Kingdom*, Health Affairs, Vol 25, No 2.

Control of pharmaceutical *profitability* (as opposed to fixing prices) is achieved through the Pharmaceutical Price Regulation Scheme (PPRS), which is negotiated periodically between the Department of Health (DoH) and the Association of the British Pharmaceutical Industry (ABPI). The PPRS covers all suppliers of brand drugs that have annual sales to the National Health Service in excess of 1 million British pounds. (This includes sales through retail pharmacy, dispensing doctors and sales to NHS hospitals). The goal of the PPRS is to both control costs of pharmaceuticals, while encouraging a strong research-based pharmaceutical industry. The system operates on the following principles:

- Companies are allowed to make a defined return on capital per year;
- Companies that exceed this defined return must repay the amount, either directly or through price reductions;
- Companies whose turnover does not match their agreed return are entitled to request price increases once per year.

Generic drugs are not covered under the UK's PPRS scheme. Instead, these drugs are listed in Category A of the Drug Tariff and their price is calculated from the list prices of two wholesalers and three generic manufacturers. Pharmacists receive reimbursement for the products that they dispense against NHS prescriptions according to the price listed on the Drug Tariff. This price has the potential to vary month by month. It is therefore in the pharmacists' best interests to source generics from suppliers that price below the Drug Tariff price, as they are reimbursed at that level regardless of what they actually pay. This scheme has helped keep generic drug prices low and competitive. While pharmacists are not allowed to make generic substitution, generic prescribing is strongly encouraged in the UK at the physician level (i.e. physicians are trained to "prescribe generically" in medical school.)

#### **Pharmaceutical Reimbursement:**

Unlike the other countries described in this document, the UK does not separate pricing and reimbursement. Once a company is granted authorization to sell their drug in the UK, reimbursement is automatically granted in full. The two exceptions to this rule involve the publication of two negative lists:

- i. The "Black List" or "Limited List" (Schedule 10) lists drugs that general practitioners are not allowed to prescribe through the National Health Service. (Physicians can prescribe these products privately, as long as they do not charge the NHS for the consultation. The patient must pay the full cost of the medication).
- ii. The "Grey List" or "Selected List" (Schedule 11) indicates products that may be prescribed only for certain specific indications or patient groups.

Statutory price cuts have been used in the UK to limit drug spending. (A renegotiation of the PPRS in 1999 saw an across-the-board price cut of 4.5%, followed by a price freeze.)

NHS patients are charged a flat co-payment for each prescription they receive. This co-payment does not apply to drugs administered in the hospital. Patients

are given the option of buying “seasons tickets” for four months or a year, which cap the total amount of co-payments that they are required to pay within that time period. A variety of individuals are exempt from paying co-payments. These include: children under the age of 16, students aged 16 to 18, or in full-time education, adults over the age of 60, expectant mothers, mothers who have had a child within 12 months, and individuals living with a number of specific conditions (diabetes, epilepsy, etc.) These groups of people represented approximately 85% of the prescriptions dispensed in England in 2000.

### ***United States***

The Food and Drugs Administration reviews drugs. In the past, once a drug had been deemed safe and effective, government sponsored drug programs immediately added the drug to their formulary. With the rising cost of drugs, many States are now looking at some of the rationalization decisions that Canada has been coping with for many years (i.e. reference based pricing, increasing co-payments and deductibles, etc.).

In order to be reimbursed by the Medicaid program and the Department of Veterans’ Affairs, manufacturers are obliged to enter an agreement in which they will provide, either a 15.1% discount off the average manufacturers price (AMP), or the difference between AMP and the best price offered to another purchaser (brand drugs). For generic drugs, a 11% discount off AMP is required.

In the private sector, there are no regulations controlling the prices of prescription drugs, although both public and private buyers influence prices through bulk buying and their ability to exclude products from their formularies.

There are no regulations regarding the pricing of generic drugs.

## **HOW DO CANADIAN GENERIC DRUG PRICES COMPARE?**

There have been a number of studies published which investigated the price of generic drugs in Canada versus other jurisdictions. The majority of these studies found that the prices of generic drugs in Canada are significantly higher than those found in comparator countries (with the notable exception of a Generic Pharmaceutical Association of Canada study, which found the prices of generic drugs in Canada and the U.S. to be comparable.) The table below summarizes some of the key findings of a selection of studies on this topic:

**Table VII: Select References: Pricing of Generic Drugs**

Authors/Year	Key Findings
Reviewed by Cockburn I, D'Cruz J, Morgan S (2006) <sup>54</sup>	<p>The focus of the report is trends in Canadian sales of non-patented prescription drugs and market structure. Results show that:</p> <ul style="list-style-type: none"> <li>• Generic drug sales have been increasing by at least 16% since 2001</li> <li>• Between 2002 and 2004, generic drug sales had the fastest annual growth rates among all market segments</li> <li>• From 2002 to 2005, the annual percentage increase in total drug sales in Canada ranged highest among the 12 countries compared (Canada, Australia, Finland, France, Germany, Italy, Netherlands, New Zealand, Spain, Switzerland, the UK, &amp; the US)</li> <li>• With the exception of Switzerland, foreign prices for generic drugs that had two to four manufacturers in Canada had lower prices than Canadian prices.</li> </ul>
Danzon, P.M., & Furukawa M.F. (2004) <sup>55</sup>	<p>The purpose of the study was to compare average pharmaceutical price levels of eight countries (Canada, Chile, France, Germany, Italy, Japan, Mexico, and the United Kingdom) to the U.S. Results show that:</p> <ul style="list-style-type: none"> <li>• Japan's prices were the highest</li> <li>• While brand name drugs were cheapest in Canada, generic prices were higher</li> </ul>
Palmer D'Angelo Consulting (2002) <sup>56</sup>	<p>The study analyses the prices of 27 top selling generic prescription drugs in Canada in 2001, which represented approximately 39% of total generic drug sales in Canada. By all measures Canadian generic prices of the sample drugs were higher than those in the U.S. Other results include:</p> <ul style="list-style-type: none"> <li>• 21 of the 27 generic drugs examined had higher prices in Canada than in the U.S.</li> <li>• On average, Canadian generic drugs were 38% lower than a comparable brand in Canada; compared to US generic drugs which are 74% lower than a comparable US brand.</li> </ul>
D'Cruz, J.R., Hejazi W., & Fleishman G (2005) <sup>57</sup>	<p>This study compares the prices of generic prescriptions in Canada and the U.S. Results showed that:</p> <ul style="list-style-type: none"> <li>• There are differences in the prices of individual generic drugs in both countries</li> <li>• From July 2003 to June 2005, generic drug prices were at parity between the US and Canada.</li> </ul>

<sup>54</sup> Patented Medicine Prices Review Board (June 2006). *Non-Patented Prescription Drug Prices Reporting: Canadian and Foreign Price* <http://www.pmprb-cepmb.gc.ca/CMFiles/Canadian-Foreign-Price-Trends-released-July-04-0638LHG-742006-1490.pdf>

<sup>55</sup> Danzon, P. M., & Furukawa, M. F. (2004). Prices and Availability of Pharmaceuticals: Evidence from Nine Countries. *Health Affairs*. October 29, 2003; W3 521--W3 526.

<sup>56</sup> Palmer D'Angelo Consulting, Inc. (2002). *Generic Drug Prices: A Canada US Comparison*. Information may be accessed at [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf)

<sup>57</sup> D'Cruz, J. R., Hejazi, W., & Fleischmann, G. (2005). *Comparisons of Retail Prices of Generic Prescription Drugs in Canada vs. United States: A Comprehensive Study*. Rotman School of Management, University of Toronto.

	<ul style="list-style-type: none"> <li>The level of regulation is one of the elements that determines the price differences between specific generic drugs.</li> </ul> <p>Researchers noted that misleading results could occur when analyzing drug price comparisons above the level of the five variables used in the Unit of Analysis.</p>
Patented Medicines Prices Review Board, Quarterly Report (June 2006) <sup>58</sup>	<p>The report provides an overview of price trends and sales, including notable price changes and international price comparisons. Findings include:</p> <ul style="list-style-type: none"> <li>In 2005, generic prescription drug prices were lower in all of the countries compared to Canada.</li> <li>Generic prescription drug prices fell in all countries in 2005; in Canada, generic prescription drug prices fell by 0.3%.</li> <li>Since 2002, non-patented branded prescription drug prices in Canada increased more than prices for patented prescription drugs and generic drugs.</li> <li>From 2004 to 2005, fifteen generic prescription drugs had price increases of over 5%.</li> </ul>
Skinner B.F. (2004) <sup>59</sup>	<p>For patented drugs, Canadian prices are close to the international median price; however, are higher for non-patented single source drugs, and for non-patented multiple source drugs. The study investigates concerns that Canadian generic drug prices are higher than American prices and Canadian non-patented drug prices are higher than the international median. The author concludes that</p> <ul style="list-style-type: none"> <li>Consumers and taxpayers could save an estimated \$810 million a year if Canadian generic drugs were priced at median international levels</li> <li>Canadian prices for generic drugs are on average 78% higher than in the United States at the retail level.</li> </ul>
U.S. FDA (2003) <sup>60</sup>	<p>Competition in the U.S. market lowers generic drug prices so they are lower than drug prices abroad. Generic drug prices in the U.S., almost 50% of all prescriptions, are cheaper than Canadian generic drugs and Canadian brand name drugs.</p>
Paris, V & Docteur E (2006) <sup>61</sup>	<p>The paper describes and assesses the pharmaceutical pricing and reimbursement policies in Canada. Findings include:</p> <ul style="list-style-type: none"> <li>Regulation has very likely been responsible for bringing Canada's prices for patented medicines roughly in line with European comparators.</li> <li>Relatively high prices of generics are explained by a lack of competition in the Canadian market.</li> </ul>

<sup>58</sup> Patented Medicine Prices Review Board (June 2006). *Non-Patented Prescription Drug Prices Reporting: Canadian and Foreign Price Trends*. Report may be accessed at <http://www.pmprb-cepmc.gc.ca/ENGLISH/view.asp?x=496>

<sup>59</sup> Skinner, B. F. (2004). *Generic Drugopoly: Why Non-patented Prescription Drugs Cost More in Canada than in the United States and Europe*. Public Policy Sources. Report may be accessed at <http://www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&id=685>

<sup>60</sup> U.S. Department of Health and Human Services, Food and Drug Administration (FDA). *FDA White Paper: Generic Drug Prices in the U.S. are Lower than Drug Prices in Canada*. Information may be accessed at <http://www.fda.gov/oc/whitepapers/drugprices.html>

<sup>61</sup> Paris V, Docteur E, *Pharmaceutical Pricing nad Reimbursement Policies in Canada* OECD Health Working Papers, 22 December 2006.

## **WHY ARE CANADIAN GENERIC PRICES INFLATED?**

Compared to other jurisdictions, Canada uses a relatively high percentage of generic drugs. As noted in the Canadian jurisdictional review above, all provincial reimbursement drug plans encourage the use of generic drugs through policies such as mandatory generic substitution, therapeutic substitution and reference based pricing. In spite of the preferential regulatory environment, generic prices in Canada remain elevated compared to other jurisdictions. As noted in the OECD report cited in the table above: "Reimbursement and other policies have no doubt played a role in the high penetration rate of generic products in the Canadian market, yet relatively high generic prices persist, suggesting that there is scope for increased efficiency of spending and cost control through policy adjustments."

Based on a review of the studies above, three main reasons for the relatively high price of generic drugs in Canada emerge: lack of competition, government policies, and to a lesser degree, exchange rate fluctuations. The following section discusses their findings.

### ***Lack of Competition***

One of the most frequently -cited reasons among the studies reviewed for Canada's high generic drug prices was the lack of competition in the generic pharmaceutical sector. Two large multi-national firms (Apotex and Novopharm/Teva) comprise the great majority of generic sales in Canada - accounting for more than half of total sales and prescriptions in the Canadian generics market.

Given the significant investment required to enter this market, other firms have not emerged to challenge the two dominant players. As a result, these companies have been successful in maintaining the prices of generics drugs at a high level. According to Skinner, this market dominance partially explains the "abnormal pricing structure for generic drugs." He further argues, however, that this dominance may be explained by some "structural economic reason or set of public policies that have historically led to artificial advantages for domestic interests over foreign competitors".

### ***Government Pricing Policies***

A number of studies suggest that current provincial reimbursement policies are also largely responsible for the elevated price of generic drugs. As Canada's largest province, Ontario's 70/90 rule eliminated the need for competition and

essentially established a maximum price for the first generic to enter the market and a price ceiling for subsequent entrants. As stated by Anis et al: "...the 70/90 rule not only failed to achieve their goal of lowering the procurement price but instead the opposite occurred. The mandated procurement price became a focal point and resulted in a clustering of prices around the maximum allowable levels with little price dispersion."<sup>62</sup> Couple this with Quebec's demand that it be given the best price in Canada, and the price of generic drugs across the different provinces have become fairly even. Because pharmaceutical companies must grant Québec price concessions given to any other province, manufacturers are hesitant to provide other, smaller provinces with further discounts. According to Palmer D'Angelo: "In essence, government policies in Canada have taken the guesswork out of generic pricing and have inadvertently stifled price competition at the same time."

### ***Generic Substitution***

Every Canadian province encourages the use of generic drugs through policies such as mandatory generic substitution. These policies encourage the use of generic drugs, but do not place any restrictions on the price of the generic. "Within the generic sector...unbranded generics compete primarily on price. Thus, in the U.S., where the generic sector is dominated by unbranded products, total generic share is 58% of units but only 18% of sales, reflecting relatively low generic prices... Canada's high generic share (59%) reflects among other things, policies that encourage use of generics such as incentives for pharmacists to substitute generics for branded drugs."<sup>63</sup>

### ***Exchange Rate Fluctuations***

According to the Danzon and Furukawa study that analyzed the difference in the prices of drugs between the US and eight other countries, while brand name drugs were cheapest in Canada, generic prices were higher. This study cited exchange rate fluctuations as a major contributor to drug price differences. "The decline in the Canadian dollar in the 1990s for example, accounts for 19 percentage points of the 33% Canada-US price differential. In addition, when drug prices are compared using GDP purchasing power parities, which standardize for cost-of-living differences...the Canada-US differential shrinks from 33% to 14%."

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<sup>62</sup> Anis A, Guh D, Woolcott J *Lowering Generic Drug Prices. Less Regulation Equals More Competition* Medical Care, 2003 Vol 41, No 1, pp-135-141

<sup>63</sup> Danzon, P. M., & Furukawa, M. F. (2004). Prices and Availability of Pharmaceuticals: Evidence from Nine Countries. *Health Affairs*. October 29, 2003; W3 521--W3 526.

## **POSSIBLE MECHANISMS TO LOWER GENERIC DRUG PRICES IN CANADA**

The majority of studies have shown that the prices of generic drugs in Canada are higher than those in other jurisdictions. Further, this paper has outlined the various reasons for higher prices such as limited competition, government reimbursement policies and fluctuations in the exchange rate. This section of the report will outline policy options to curb generic drug prices in Canada.

### ***I. Expand the Mandate of the PMPRB***

The PMPRB regulation of brand pharmaceuticals has been considered responsible by some<sup>64</sup> as the reason Canada's patented drug prices are comparable with countries in the European Union. Expanding the mandate of the Board to regulate the prices of non-patented medicines could help moderate generic prices in Canada.

#### **Pros**

According to the PMPRB's annual report, Canadian prices have moved closer to median international prices since price regulation commenced in 1987. In 1987, Canadian prices for patented medicines exceeded the international median by more than 20%. After fairly consistent annual decreases until 1994, the prices of patented medicines in Canada have since stabilized at (or up to 10% below) the median of prices in seven comparator countries. In 2005, prices of patented drugs in Canada were about 8% lower than the median prices of the seven comparator countries. These data suggest that Canadian price regulation has had a dampening effect on relative price levels in Canada, bringing them closer to the median price paid in a selected set of countries.

The PMPRB has already established the necessary infrastructure, expertise, data, and methodology to regulate drug prices and broadening its mandate to include non-patented medicines should be a relatively straightforward exercise. Furthermore, federal, provincial and territorial (FPT) jurisdictions have agreed that ongoing reporting of information on the price of non-patented drugs would be beneficial and in 2005 the FPT Ministers of Health announced the endorsement of the PMPRB to monitor and report on the prices of patented non-prescription drugs. This endorsement from the FPT Ministers of Health suggest that they may be supportive of expanding the PMPRBs' role. Although the PMPRB is a Federal quasi-judicial body that reports to Parliament through the Federal Minister of health, such support from the provinces would prove key to helping broaden the Board's mandate.

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<sup>64</sup> Paris V, Docteur E, *Pharmaceutical Pricing nad Reimbursement Policies in Canada* OECD Health Working Papers, 22 December 2006.

## **Cons**

Whether or not the PMPRB has a significant constraining effect on average pharmaceutical price levels in Canada, it is likely that price regulations will have deleterious impacts. For example, the variation in price levels seen across Canada may be more limited than would otherwise exist in the absence of price regulation. Manufacturers may sell products to some purchasers with limited market power at lower prices than those purchasers could otherwise command because of concern about the PMPRB authority to assess not only average prices paid, but to single out particular prices paid in particular geographic areas by particular purchasers.

Furthermore, there is the possibility that regulation of generic prices will not have the anticipated effect of lowering overall prices. According to H. Lofgren, “the highest market share [of generic drugs] is found in countries where historically the industry has had great pricing freedom, such as the Netherlands, the UK, the US, and Germany.”<sup>65</sup>

Another point may be that regulating generic prices at the federal level may not be as effective for generics given the existing regulatory environment for generic prices at the provincial level.

## ***II. Promote Competition in the Generic Manufacturing Sector***

As noted earlier, the Canadian generic drug market is dominated by two major players. Government incentives to “start up” generics companies may help increase the number of players and thus increase the amount of competition, which may allow for competitive market forces to take over and cause the price of generic drugs to decrease.

## **Pros**

Providing incentives for the expansion of the generic pharmaceutical manufacturing in Canada provides opportunities for growth in capital investment, jobs, research and development and tax revenue.

Promoting a competitive environment for generics may encourage companies to broaden the selection of off patent products that are chosen to be “genericized”. This would provide benefits both therapeutic (broader array of therapeutic agents) financial benefits (reduced drug plan costs) to the health care system.

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<sup>65</sup> Lofgren, H. (2002). *Generic Drugs: International Trends and Policy Developments in Australia*. Pharmaceutical Industry Project: Equity, Sustainability, and Industry Development Working Paper Series. Center for Strategic Economic Studies: Victoria University of Technology, Australia

## **Cons**

Given the significant costs associated with starting a generic pharmaceutical company, it would take a number of years for other Canadian companies to enter this market.

### ***III. Eliminate government interference***

One of the main reasons for the high prices of generics drugs in Canada cited by researchers has been the provincial government pricing policies for generic drugs. If the Ontario government were to abolish its' 70/90 rule (now 50/90), manufacturers would no longer have this number as a (high) benchmark price. Furthermore, it has been argued that for the generic sector, price freezes have the effect of maintaining prices at an artificially high level: in a free market system, the prices of generic drugs tends to decrease with time, whereas in Canada, lengthy price freezes have ensured the continued elevated price of generic drugs.

## **Pros**

Lack of government interference may allow market forces to take over and decrease the price of generics drugs.

## **Cons**

Given the lack of competition in the Canadian market, it is appears highly unlikely that this strategy would produce the desired effect.

### ***IV. Monopsonist Model with International Competition***

Based loosely on the New Zealand model, this concept involves the creation of a National Formulary with the government as a sole supplier for the country. The government purchaser will tender a contract to generic manufacturers (one company per product) and the lowest bidder receives the right to supply the entire Canadian market. The government can reserve the right to expand tenders to include international generics companies (e.g. from India, Brazil the US and China) to ensure a strongly competitive market. (This model can also be adapted to a provincial market.)

## **Pros**

The ability to extend tenders to international manufacturers will guarantee an increase in competition in the Canadian market. This competition in particular will drive the price of generics drugs down.

## **Cons**

Limiting consumer choice to just one drug per condition is a risky and very restrictive concept. While New Zealand has been able to provide drug coverage

for its' entire population with a single low co-payment, many critics have argued that the restrictive nature of the model is detrimental to the health of its citizens.

International regulations for importation of drugs will also need to be reviewed, re-evaluated, and renegotiated in order for this model to work.

### ***V. Profit Controls for Generic Companies***

Modeled after the Pharmaceutical Price Regulation Scheme in the UK, this model would involve control of generic manufacturers' *profitability*, as opposed to regulating *prices* of generic compounds. The underlying tenets of this model suggest that in order for a product to be reimbursed by the government, the manufacturer will agree to making a defined return on capital per year. Companies that exceed the defined return must repay the amount and those companies who do not match the agreed-upon return are entitled to request a price increase. Given that the *costs* associated with research and production of generic drugs is fairly low, and their relatively *high* price in Canada, it is likely that generic producers currently enjoy a healthy profit margin. This model attempts to provide a fair profit margin, while controlling costs of pharmaceuticals.

#### **Pros**

It is likely that this model would have the desired effect of decreasing the price of generic drugs in Canada.

#### **Cons**

While this model ensures a "fair" profit margin for the producer, it is evident that the definition of fair is likely to be contentious. In order for this model to be effective, the model would have to be implemented on a Canada-wide level, and Canada does not currently have a pan-Canadian drug strategy. Enforcing this paradigm will take a serious cultural shift in thinking about prescription drug reimbursement.

### ***VI. "International Reference Based Pricing for Generic Drugs"***

British Columbia currently uses the concept of reference based pricing (RBP) in an attempt to keep the costs of pharmaceutical expenditures in check. This model suggests an expansion of this concept to include reference drugs from international sources. In this model, the Canadian (or provincial) government will introduce a scheme wherein generic drugs for certain conditions will be reimbursed only at a 'reference price'. This reference price will be set at the lowest price for a generic product that they can find – *from a select group of countries*.. Products will still be produced in Canada, but the price paid for the product will be referenced at an international level.

**Pros**

Given the low cost of generic drug production in countries like India and Brazil, it is a near certainty that this model will reduce the price of generic drugs in Canada.

**Cons**

Experience with “Canadian Generic pricing” in British Columbia has garnered mixed results, and a general lack of consensus on whether RBP produces actual savings to the government. Patients often lose in this equation as the generic drug with the appropriate reference price can change on a regular basis, causing patients to have to switch medicines periodically.

This model also limits access to a range of products, unless the patient has the ability to pay for the difference in price between the reference drug, and the drug they need.

***VII. Reduce the 50% rule to a “reasonable” level***

According to new government legislation, the Ontario government currently requires that the first generic drug to be reimbursed by the Ontario Drug Benefit be priced no higher than 50% of the price of its brand name equivalent. As stated previously in this paper, it has been argued that this type of regulation is partially responsible for maintaining the prices of generic drugs at an artificially elevated level: what was supposed to be a price ceiling, has in effect had the opposite effect, and has provided generic manufacturers with a “price floor”. An alternative to eliminating this type of government ‘interference’ altogether is to suggest a more realistic and reasonable percentage for generic prices. A formula that takes into account the real cost of research and production of the generic drug and incorporates a reasonable return on investment is suggested. The “50% rule” would then become the “20% rule” or the “30% rule”.

**Pros**

This is perhaps the option that would be the easiest to implement as the Ontario government already employs this strategy. Once the formula is established, (and it is assumed that the appropriate percentage would be somewhat less than 50%) the price of generic drugs would fall in Ontario. As Quebec requires that they receive the best available price in Canada, they too would be given this lowered rate. The rest of Canada is likely to follow suit.

**Cons**

The generics drug industry has become used to elevated profits and a healthy return on investment and are unlikely to approve of this increased government interference. They have proved in the past that they are not averse to taking their position to court and will likely do so again. Lobbying and resistance from this sector would be fierce.

### ***VIII. Cross Border Importation on Generic Drugs from the US***

A few years ago, the comparatively low price of brand name drugs in Canada attracted the attention of decision makers in the US when a number of Canadian pharmacies began selling 'cheaper' Canadian drugs to US residents over the internet. This prompted a number of States to consider implementing programs for their residents that would solidify the practice in an effort to curb rising drug costs. State and city-run programs were implemented that allowed participating members to buy their drugs from 'approved' Canadian web sites. The discussion on this practice (and the associated controversy) continues to this day.

Canada's comparatively cheap brand name drugs make this an attractive option for US residents. As noted earlier, generic drugs in the US are significantly cheaper than they are in Canada. This model suggests allowing a 'reverse' cross border internet pharmacy scheme whereby Canadian citizens would purchase their generic drugs from approved American internet sites.

#### **Pros**

Given the price of generic drugs in the US, the Canadians who purchase their drugs via this method will receive a break in the price of their drugs. Purchasing repeat prescriptions via mail order is a common practice in the US, therefore the infrastructure to support such an option is already in place.

#### **Cons**

As it currently stands, cross border internet pharmacies are technically illegal. A concern with cross border internet pharmacies is that it removes the drugs in question from the tight regulatory controls that help protect the safety of consumers. Once out of the regulatory channels, the drugs are no longer subject to recalls for example. These hurdles will have to be investigated and overcome in order for this to be a viable option. Furthermore, Canadians are less comfortable with the concept of mail order pharmacies and a significant cultural shift will have to take place in order for Canadians to be comfortable with this concept.

### ***IX. Bulk Buying of Generic Drugs***

Given the fact that the provincial governments collectively are the largest purchasers of drugs in Canada, this gives them some clout where prices are concerned. This model suggests that the disparate governments unite to investigate the possibility of buying generic drugs in bulk in order to negotiate lower prices.

**Pros**

Bulk buying is one of the main pillars of the proposed National Pharmaceutical Strategy and the concept is currently being examined. This concept therefore is clearly considered a viable option from the governments' perspective.

**Cons**

The provinces do not, for the most part, cooperate on the delivery of health services. Their choices and decisions are made independently from each other. This model would require considerable inter-provincial cooperation. Furthermore, this model may suggest a national formulary, for which much opposition exists.

## CONCLUSION

Generic drug prices are not regulated by the Federal government in Canada, however a number of provinces impose regulatory restrictions upon generic manufacturers if they wish to have their products reimbursed by the province. Regardless of this, a number of studies have concluded that the price of generic drugs in Canada are higher compared to other international jurisdictions. It has been argued that prices are higher due to a general lack of competition among generic manufacturers, government pricing policies, and to a lesser extent, exchange rate fluctuations.

The paper outlines a number of options that may prove effective in lowering generic drug prices. These include expanding the mandate of the PMPRB to include regulation of generic drugs; promoting competition within the generic drugs manufacturing sector, eliminating government interference, a monopsonist model with international competition, profit controls for generic companies, international reference based pricing, a reduction in the “50% rule”, cross border importation, and bulk buying of generic drugs.

It is apparent that some of the suggested models may be more appropriate and feasible than others, such as expanding the mandate of the PMPRB, reducing the “50% rule”, bulk buying and cross border importation.

CTAC recommends that funding be provided in order to convene a focus group of experts and other appropriate individuals to discuss these options in more detail. Experts to be recruited include Federal/Provincial and Territorial (F/P/T) representatives, pharmaco-economic experts, health science industry members (representatives from both brand and generic manufacturers), physicians, patients and pharmacists. These individuals would be charged with examining the issue and providing expanded recommendations to the government.

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