Submission of

Canadian Generic Pharmaceutical Association (CGPA)

New Brunswick
Fair Drug Prices Consultations

August 12, 2011

Canadian Generic Pharmaceutical Association
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About the Canadian Generic Pharmaceutical Association (CGPA)

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic pharmaceutical industry. The industry plays an important role in controlling health-care costs in New Brunswick. Generic drugs are dispensed to fill approximately 62 percent of all prescriptions in New Brunswick but account for only 33 percent of the $10-million New Brunswickers spent on prescription medicines in 2010.

Member companies of CGPA represent more than 90 percent of the Canadian generic pharmaceutical market by sales. The following companies are members of CGPA.

Finished Dosage Manufacturers

Apotex Inc.
150 Signet Drive
Toronto (Weston), Ontario
M9L 1T9
Tel: 416-749-9300
Fax: 416-401-3849
www.apotex.ca

Apotex Fermentation Inc..
50 Scurfield Blvd.
Winnipeg, Manitoba
R3Y 1G4
Tel: 204-989-6830
Fax: 204-989-9160
www.apoferm.mb.ca

Cangene - Corporation
104 Chancellor Matheson Road
Winnipeg, Manitoba
R3T 5Y3
Tel: 204-275-4200
Fax: 204-269-7003
www.cangene.com

Cobalt Pharmaceuticals Inc.
6500 Kitimat Road
Mississauga, Ontario
Canada L5N 2B8
Tel: 905.814.1820
(1.866.254.6111)
Fax: 905-814-8696
(1.866.260.6292)
www.cobaltpharma.com

Mylan
85 Advance Road,
Etobicoke, Ontario,
M8Z 2S6
Tel: 416-236-2631
Toll Free North-America: (877) 540-7377
Fax: (416) 236-2940
www.mylan.ca

Pharmascience Inc.
6111 Ave Royalmount, Suite 100
Montréal, Quebec
H4P 2T4
Tel.: (514) 340-9800
1-800-363-8805 CDA & US
Fax: (514) 342-7764
www.pharmascience.com

Ranbaxy Pharmaceuticals Canada Inc.
2680 Matheson Blvd. E., Suite 200
Mississauga, Ontario
L4W 0A5
Tel: 905-219-8820
Fax: 905-602-4216
Toll Free: 1-866-840-1340
www.ranbaxy.ca

Sandoz Canada Inc.
145, Jules-Léger
Boucherville, Quebec
J4B 7K8

Tel: 450- 641-4903
Toll Free: 1-800-343-8839
Fax: 514- 596-1460
www.sandoz.ca

Taro Pharmaceuticals
130 East Drive
Brampton, Ontario
L6T 1C1

Tel: 905-791-8276
Fax: 905-791-4473
www.taro.ca

Teva Canada Limited
Corporate Head Office
30 Novopharm Ct.
Toronto, Ontario
Canada M1B 2K9

Tel: 1-800-268-4127
Fax: 416-291-1874
www.tevacanada.com

Industry Suppliers/Active Ingredient Manufacturers

ACIC
81 Sinclair Boulevard
Brantford, Ontario
N3S 7X6

Tel: 519-751-3668
Toll Free: 800-265-6727
Fax: 519-751-1378
www.acic.com

Contract Research Organizations

Cetero Research
4520 Dixie Road
Mississauga, Ontario
L4W 1N2

Tel: (905) 238-0599
Fax: (905) 629-5796
www.cetero.com

Anapharm
2500 rue Einstein
Québec City, Quebec
G1P 0A2

Tel: (418) 527-4000
Toll Free: 1-800-831-4001
Fax: (418) 527-3456
www.anapharm.com
www.pharmanet.com

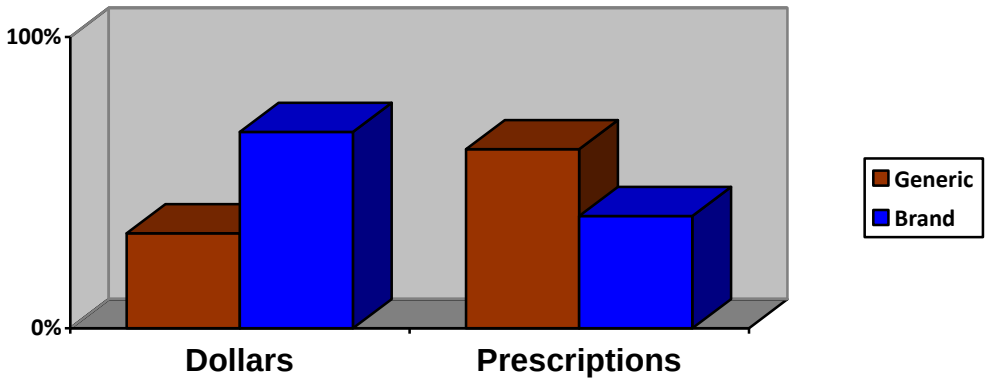
Pharma Medica Research Inc.
6100 Belgrave Road
Mississauga, Ontario
L5R 0B7

Tel: 905-624-9115
Toll Free: 1-888-PHARMA1
Fax: 905-624-4433
http://www.pharmamedica.com

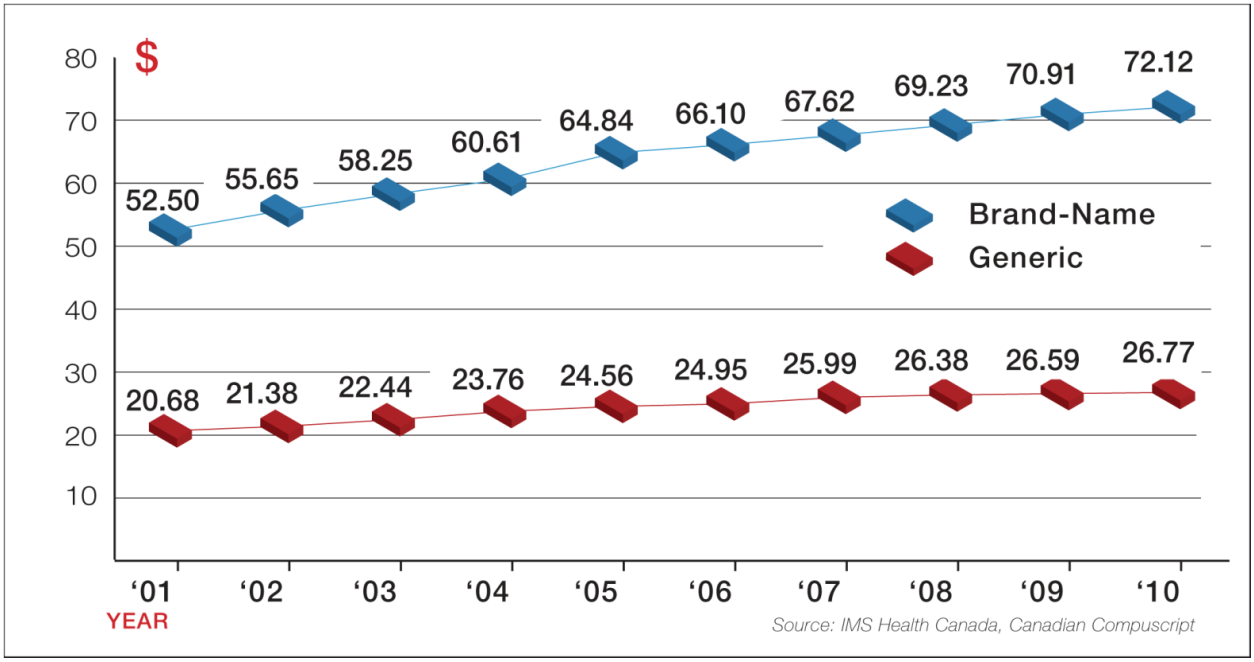
Health Care Savings

New Brunswick Prescription Drug Market
(Source: ims brogan, 2010)

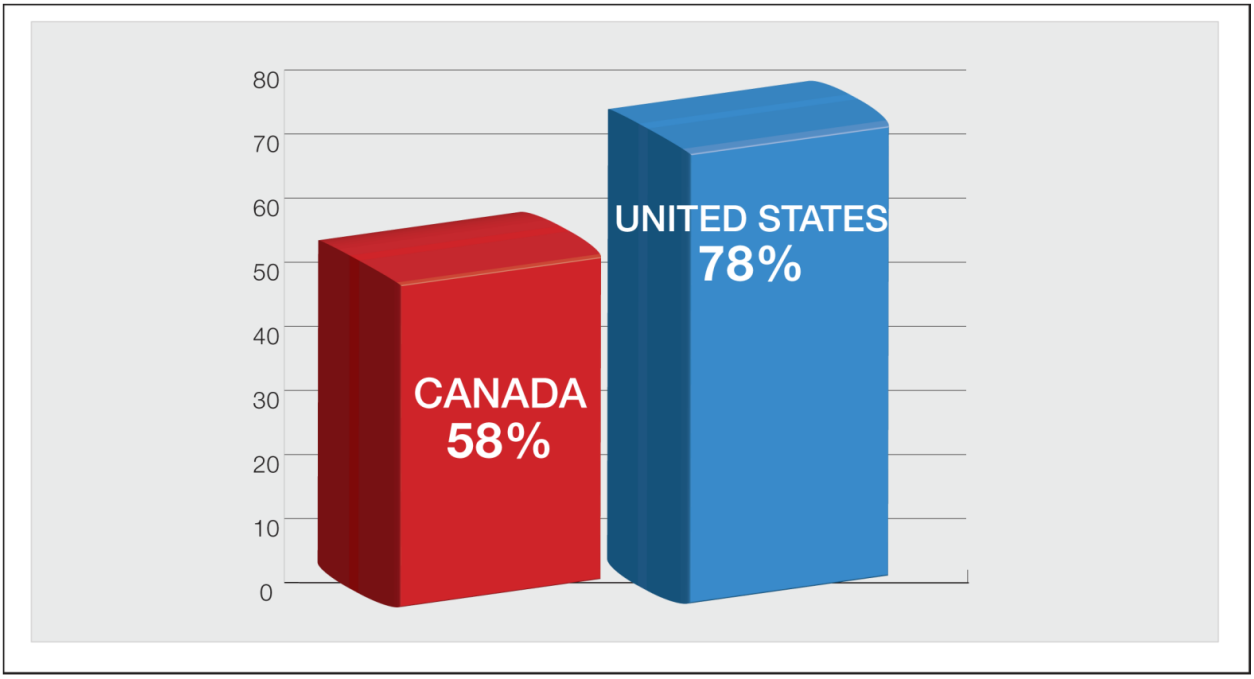
Generic drugs are dispensed to fill approximately 62 percent of all prescriptions in New Brunswick but account for only 33 percent of the $10-million New Brunswickers spent on prescription medicines in 2010.



Price Per Prescription: Generic Versus Brand-Name
(Source: ims brogan)



Generic Percentage of Total Market: Canada vs. United States



If the use of generic drugs in Canada was equal to that in the United States, Canadians would have saved an additional $3.5-billion in 2010.

Savings for each 1% increase in use of generic drugs

PROVINCE	TOTAL SAVINGS	PUBLIC SAVINGS	PRIVATE SAVINGS
British Columbia	$21,500,000	$8,600,000	$12,900,000
Alberta	$18,500,000	$8,700,000	$9,800,000
Saskatchewan	$5,500,000	$3,100,000	$2,400,000
Manitoba	$7,400,000	$3,500,000	$3,900,000
Ontario	$96,300,000	$43,400,000	$52,900,000
Quebec	$70,000,000	$36,200,000	$33,800,000
New Brunswick	$6,000,000	$2,000,000	$4,000,000
Nova Scotia	$6,500,000	$2,800,000	$3,700,000
P.E.I.	$800,000	$300,000	$500,000
Newfoundland	$3,500,000	$1,300,000	$2,200,000
Canada	$236,000,000	$109,900,000	$126,100,000

Source: CGPA calculations based on IMS Brogan data and CIHI public private market share.

CGPA Principles for Pricing and Reimbursement

NO TENDERING – **Open formulary for all manufacturers**. Tendering creates a "winner-take-all" scenario that removes incentives for generic manufacturers to bring new products to market.

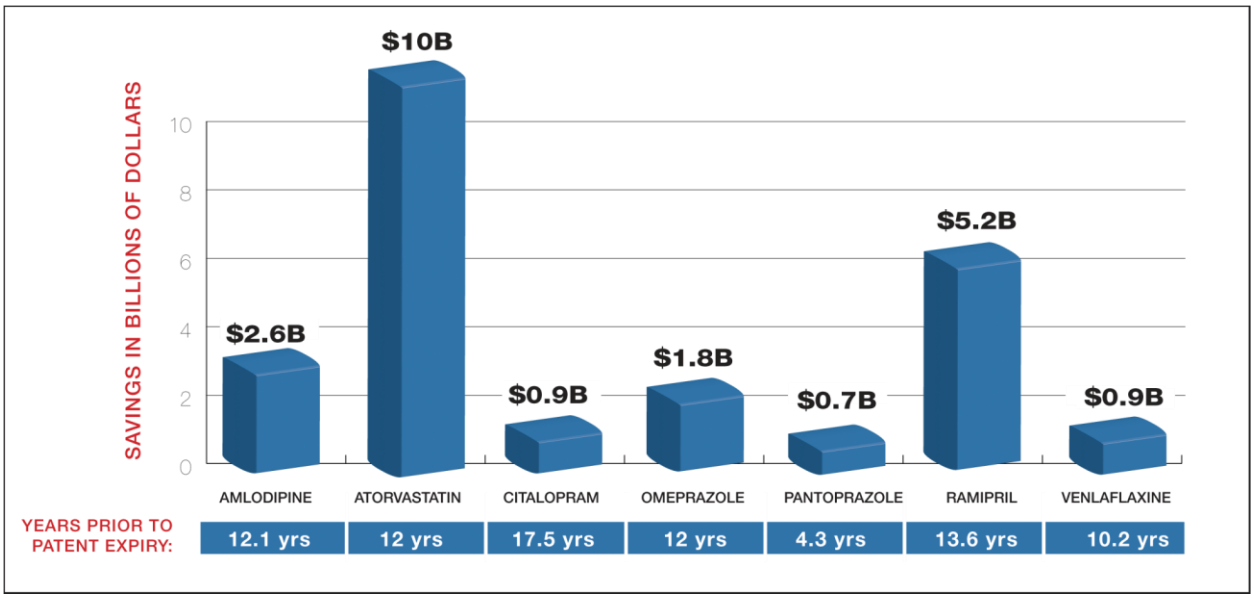
RULES FOR FORMULARY LISTINGS and pricing mechanisms for all products (patented and multi-source) must be clear and fully transparent. The must be no confidential listing agreements with brand-name manufacturers after generic versions become available.

MONTHLY FORMULARY LISTINGS for interchangeable multi-source drug products to take full advantage of available savings. Other provinces, such as British Columbia, Alberta, Saskatchewan, Ontario and Nova Scotia have coupled drug plan reforms with faster generic formulary listings.

INCENTIVE PERIOD for generic pharmaceutical manufacturers in order to provide incentives to make the sizable investments, and undertake the significant risks, required to bring new cost-saving generic pharmaceutical products to market.

The Health Council of Canada's June 2010 report *Generic Drug Pricing and Access: What are the Implications?* recommended that incentives be provided for generic pharmaceutical manufacturers to launch new cost-saving products.

Seven of the 10 top-selling drugs in Canada were launched as a result of generic pharmaceutical companies' litigation saving Canadians an additional $22-bilion.



EXCEPTIONS process to ensure the availability of existing generic products and in recognition that some products are more difficult and/or costly to develop and/or produce.

List prices must be applicable to **ENTIRE MARKET** (public and private).

FAIR PHARMACY COMPENSATION to reduce reliance on manufacturers' allowances while preserving the services community pharmacies provide to New Brunswickers.

Prices paid for generic pharmaceuticals include significant support for the services community pharmacies provide to New Brunswick patients. Any changes to the pricing and reimbursement system for generic drugs must ensure those patient services are maintained.

"Given the funding gap, it must be recognized that pharmacy sustainability and the pharmacy services Canadians have come to expect, are linked in part to the price of generic drugs. As government drug plans seek to reduce generic drug prices, the funding gap will worsen unless appropriate changes are made to the reimbursement model for pharmacies."

Nadine Saby, President and CEO
Canadian Association of Chain Drug Stores
September 24, 2008 Speech to Economic Club of Toronto

PHASE-IN OF REFORMS/PRICE REDUCTIONS to allow all players in the supply chain (manufacturers, pharmacies and wholesalers) to adapt. There must also be adequate time to implement alternative funding sources for pharmacies.

The CGPA recommends a joint Working Group (CGPA/NB) to deal with implementation of the new regime.

Ensuring Reforms Benefit All New Brunswick Residents

As stated above, the equal application of pricing rules for prescription medicines for all New Brunswick residents, whether they are covered by the New Brunswick government's drug benefit plan, an employer- or union-sponsored drug benefit plan, or pay for their prescriptions out of pocket, is an important principle for CGPA.

Other jurisdictions that have recently undertaken reforms of their drug programs, such as Ontario, Quebec, British Columbia, Alberta, Saskatchewan and Nova Scotia, have ensured that the associated reductions of prices of prescription medicines have also applied to prices of drugs in the private payer market, which, according to the Canadian Institute of Health Information (CIHI) comprises 56 percent of the total Canadian prescription drug market.

According to data from the Government of New Brunswick, fully 75-85% of New Brunswick residents are covered by a private drug plan or pay for their prescriptions out-of-pocket. It is, therefore, all the more important that all New Brunswick residents benefit from any reforms.

Preventing Predatory Pricing Tactics

Brand manufacturers typically lose the vast majority of their market share for particular drugs upon the entry of less expensive generic competitors. Some brand companies, aware of pending patent expiries, attempt to implement predatory pricing tactics such as dropping their prices just prior to patent expiry, in order to completely deflate the price governments will reimburse for generic drugs and, thus, undermine generic competition.

New Brunswick must prevent anti-competitive tactics by brand companies by reimbursing for generics at higher levels if a brand company has lowered its price in the 24 months prior to the entry of a generic manufacturer.

The Governments of British Columbia, Alberta and Ontario have recognized the possibility of such abusive behaviour and have provided for an exception to their reimbursement levels if brand companies have dropped their price by more than 20 percent in the past 24 months.

Exceptions to New Pricing Levels

Any changes to the pricing for multi-source interchangeable drug products must provide for exceptions to ensure the availability of current generic products and future generics. To achieve this, there should be clear rules established for exceptions for:

- *Existing products* that are costly and/or difficult to develop and/or produce

- *Incentive period* for generic pharmaceutical manufacturers to make the investments required to bring new cost-saving medicines to market. The Government of Ontario has implemented an incentive period for generic pharmaceutical products that were brought to market early due to successful litigation by generic manufacturers. This Incentive Period comes into force in April 2012. During a specified period (three months or more at the discretion of the Executive Officer) there will be a premium price for these products. The Government of Quebec has agreed that it will match Ontario prices for this period. The Government of New Brunswick must ensure that it provides enough flexibility in its pricing rules to take advantage of these new cost-saving products. If a higher price is available in Ontario and Quebec, which comprise approximately 60 percent of the Canadian market, it is unlikely that manufacturers would sell the product at a lower price in New Brunswick. This would mean that, at least during the Incentive Period, New Brunswickers would be left paying for the higher-priced brand-name versions of these products.

- *Single or dual source products*. Few competitors reflect the market reality that these products have low volumes and/or margins. There must be exceptions to ensure their continued availability

CGPA recommends a New Brunswick/CGPA Implementation Working Group be established with regular calls/meetings to discuss implementation of the new pricing regime.

Further Clarification regarding the "Incentive Period"

When a generic manufacturer brings a product to market early after successfully litigating the brand's patent, there are huge savings for New Brunswick's public and privately funded drug programs. New Brunswick taxpayers and patients often stand to save millions of dollars over what would have been spent had the generic manufacturer not successfully challenged the brand's patents.

As per the graph on page 5 of this submission, fully seven of the 10 top-selling generic drugs in Canada were brought to market prior to the expiry of the final patent or patents on the brand version saving Canadian payers approximately $22-billion.

In bringing these products to market, however, generic manufacturers incur significant litigation costs and exposure to court-awarded damages.

In its June 2010 report, *Generic Drug Pricing and Access in Canada: What are the Implications?*, the Health Council of Canada recognized that it is beneficial to the health-care system for generic manufacturers to challenge patents and that there must be incentives to encourage generic market entry at the earliest appropriate opportunity. Such litigation results in significant savings for provincial and private payers.

In the absence of such litigation, brand-name pharmaceutical companies would be encouraged to game the patent system to delay generic entry, leading to additional expenditures of billions of dollars for prescription medicines. Supplementary patents are becoming extremely common, and the average blockbuster drug in Canada is now protected by many patents.

Establishment of Rules for Price Increases

The Government of New Brunswick should also ensure that there are price increase mechanisms for generic pharmaceutical products to allow for the continued supply of cost-saving generic prescription medicines.

All input costs are subject to increases, which may require the manufacturer to seek a price increase or stop making the product.

Some generic products have been on the market for many years. For these products, there might not even be a reference brand-name drug. Some of these products have few competitors, which reflect market realities (low volumes and/or margins).

Distribution Fees

CGPA recommends that, should the Government of New Brunswick introduce reductions to reimbursed prices for multi-source interchangeable drug products as part of its reforms, it assume the payment of distribution fees for these products as the Government of Quebec did in October 2010.

Faster Generic Formulary Listings

The Government of New Brunswick has indicated that it plans to implement an abbreviated formulary listing process for multi-source interchangeable drug products after they are approved by Health Canada in order to maximize savings.

CGPA supports the New Brunswick government on this important cost-saving initiative.

Other provinces, such as British Columbia, Alberta, Saskatchewan, Ontario and Nova Scotia, have coupled drug plan reforms with faster generic formulary listings.

Decisions regarding whether or not to fund a new drug can be difficult. Payers must weigh the additional costs of listings a new medicine against its relative therapeutic value.

In contrast, the decision to list a generic version on a drug plan formulary once it has received its Notice of Compliance (NOC) from Health Canada is easy: Do you want the same thing for less money?

> "Provincial and territorial drug plans could ensure that newly approved drugs are listed on their formularies in a timely manner. Currently, the formulary listing process can take several months from the time the drug has received its NOC from Health Canada. This delay in listing newly approved drugs results, for instance, in public drug plans paying additional money for a brand name drug, even though a lower-cost generic version is available."
>
> GENERIC DRUG PRICING AND ACCESS IN CANADA: WHAT ARE THE IMPLICATIONS?
> Health Council of Canada, June 2010

The Health Council of Canada's June 2010 report *Generic Drug Pricing and Access: What are the Implications?* recommended that provinces list generics on their formularies more quickly.

CGPA recommends that the Government of New Brunswick implement monthly formulary listings for interchangeable multi-source drug products to take full advantage of available savings.

Recommendations for Implementation of Expedited Generic Formulary Listings

An ideal submission will include:

1. Notice of Compliance with Declaration of Equivalence
2. Product Monograph
3. Pricing Information
4. Access letter
5. Confirmation of Availability letter
6. Bio Synopsis (includes protocol and summary)

There should be a fixed deadline date for submission and a fixed date for formulary updates. For example, complete submissions filed by the 15th of each month, will products listed at the beginning of the following month.

No additional review is necessary if the product has a Declaration of Equivalence which shows that the product was approved on the basis of a comparison. Manufacturers work with Health Canada regarding the Reference product. If it is not the Canadian Reference product, the sponsor must prove to Health Canada that the Reference Product chosen is an appropriate reference product. CGPA believes that any additional review is duplicative and unnecessary.

Submission sponsors should not be required to pay a submission review fee as no consultant review should be necessary.

Product samples, pictures or artwork should not be required as part of the submission. These requirements are not required by most provinces. Product descriptions are part of the Product Monograph. Dealing with product samples may become problematic for the regulator in terms of storage, security and disposal.

Electronic submissions should be accepted. Member companies CGPA would be willing to provide New Brunswick with beta test examples of submissions sent to other provinces.