

**Submission to the Patented Medicines
Prices Review Board**

Revised Draft Board Excessive Price Guidelines

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

Canadian Generic Pharmaceutical Association

April 27, 2009

Canadian Generic Pharmaceutical Association

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Dear Dr. Benoit,

Please find enclosed the submission of the Canadian Generic Pharmaceutical Association (CGPA) with respect to the Board's Revised Draft Excessive Price Guidelines published on March 27, 2009.

While CGPA and its member companies have never accepted the PMPRB's claims of jurisdiction over generic products with patents, the generic pharmaceutical industry has worked cooperatively with the PMPRB Board and staff over the past two years in an attempt to develop guidelines that reflect the market realities for generic medicines in Canada.

As noted in earlier correspondence, CGPA and its member companies are extremely disappointed with the Board's decision to withdraw the thoughtful and workable proposals for patented generic medicines that were developed by a working group of PMPRB staff and CGPA members over the course of two years. The decision to take the proposal to exempt patented generic products from the Highest International Price Comparison (HIPC) Test will be particularly problematic for any generic company that has a patent on a product.

With exception to the introductory price test, the Board's latest proposed guidelines would subject patented generic medicines sold in a competitive, multi-source environment to the guidelines developed for brand-name medicines sold in a monopoly environment. This is completely unacceptable to the generic pharmaceutical industry.

The PMPRB was created in 1987 when monopoly patent rights were significantly expanded for brand-name drug companies. At that time, Parliament was clear that the Board was established to protect against excessive prices and was intended to focus on drugs which had no competitors.

The PMPRB has existed for almost 20 years without jurisdiction over generic drugs. The PMPRB is now taking an expansive approach to interpreting its mandate and claims that the *Patent Act* requires all patentees to file and report information on prices, sales and R&D spending – including generic products covered by patents that are sold in a competitive, multi-source environment.

There are two primary situations under which a generic product may be covered by a patent. A generic company may obtain a patent to cover innovative processes it has developed, such as processes to make more efficient use of raw materials and increase yields. A generic company may also obtain a license to sell the actual brand-name drug product manufactured by the brand-name company as a generic once generic competition can enter the market. Neither situation conveys a market monopoly or pricing power for a patented generic.

This proposed expansion of the PMPRB's mandate ignores the original policy intent of the PMPRB. CGPA does not agree with the PMPRB's assertion that it has legal jurisdiction over generic drug products with patents. Nor do we believe the PMPRB Excessive Pricing Guidelines, which were developed to regulate monopoly brand-name drug prices have either the certainty or the flexibility to deal with the generic market. The Board's decision would also impose a very large regulatory burden in a low-margin, highly competitive sector without providing any benefits to Canadians.

CGPA has been unable to identify any legal, administrative or other impediments that would prevent the Board from developing a separate approach to dealing with patented generic drugs, which are sold in highly competitive situations. It should be noted that there is already precedent for this approach in the PMPRB's complaint-based regulation of over-the-counter (OTC) drugs and veterinary drugs.

The pricing of generic drugs remains a provincial jurisdiction in Canada, and there is fierce competition for market share amongst generic manufacturers once brand patent issues are resolved and generic products are allowed to enter the market. No market or price advantage can be obtained by the holder of a generic patent, and no public benefit can be achieved through adding an additional layer of price regulation on some generic products. Generic drug prices cannot be effectively regulated through the *Patent Act*.

Generic drugs continue to provide excellent value for Canadians. Even though generic drugs are dispensed by pharmacists to fill more than 50% of all prescriptions in Canada, they account for only 23% of the \$20-billion that Canadians spent on prescription medicines in 2008. The provinces of Ontario and Quebec have recently made significant changes to the way in which generic drugs are priced in their jurisdictions, which has already generated hundreds of millions of dollars of further cost savings. Other provinces are currently reviewing the methods for determining reimbursement pricing for generic drug products in their jurisdictions.

As the maximum allowable prices for generic medicines set by the province are always lower than the non-excessive domestic brand price set by the PMPRB, the price of a patented generic cannot be deemed to be excessive. An international price comparison should not be required.

The Board's proposed approach to patented generics is completely unwarranted and must be abandoned. CGPA and its member companies urge the Board to remove patented generics from the scope of its final Excessive Price Guidelines. If the Board is unwilling to take this step, then adoption of the recommendations of the CGPA-PMPRB Working Group would be the most appropriate alternative.

Thank you for taking the time to review this submission. CGPA remains available to discuss this matter further with the Board and PMPRB staff.

Sincerely,

A handwritten signature in black ink that reads "Jim Keon". The signature is written in a cursive style with a large initial "J" and "K".

Jim Keon, President

Part One: Background

CGPA Position Statement

The Canadian Generic Pharmaceutical Association and its member companies do not accept that patented generics are now or should be covered by the PMPRB Board's Excessive Price Guidelines, and the following comments are made without prejudice to this position.

The generic pharmaceutical industry is strongly opposed to the current proposed guidelines, which subject patented generic products to guidelines developed to reflect brand-name pricing realities.

Placing an additional layer of price regulation on some competitors in the generic market will create market distortions, discourage innovation by generic manufacturers, and place a significant administrative filing burden on manufacturers without providing any benefits to Canadian society. It will place an enormous budgetary burden on taxpayers, but will not lead to lower generic prices as the pricing of generic drugs is a provincial jurisdiction.

CGPA and its member companies feel the inclusion of patented generics is an example of unnecessary price regulation and should therefore not proceed. If the Board feels it must proceed, it remains the view of CGPA and its member companies that the market realities facing generic products are unique, and separate guidelines are required for patented generic medicines. Any regulatory burden imposed on patented generic manufacturers must be proportionate to the resulting benefit for society and consumers.

CGPA has demonstrated its willingness to work with the Board and its staff toward developing a regulatory regime that will fulfill its desired objectives. However, the generic industry is not prepared to submit to guidelines developed in consultation with brand companies, for the regulation of brand companies as a result of legislation benefiting brand companies.

Generic Manufacturers and Patents

There are two primary situations where a generic drug may be covered by a patent:

- A generic company may obtain a patent to cover innovative processes it has developed, such as processes to make more efficient use of raw materials and increase yields.
- A generic company may obtain a license to sell the actual brand-name drug product manufactured by the brand-name company as a generic (known as an "authorized generic") once generic competition can enter the market.

There is no known case where a patent held by a generic company resulted in a market monopoly or which conveyed pricing power. Under no circumstances do generic patents held for process efficiencies prevent other competitors from entering the market, and therefore do not prevent or hinder competition. In the case of authorized generics, by definition, brand companies only allow such authorizations in the face of competition, not in monopoly situations. In all cases, the generic drugs are introduced at prices below those of the corresponding branded product.

Part Two: Policy Considerations

General Policy Implications

The PMPRB has not articulated the public policy benefit associated with the proposed guidelines as they pertain to patented generic medicines, but the negative impacts for generic manufacturers will be significant. These include (but are not limited to):

- The proposed guidelines will create a dual price regulation regime (provincial and federal) for patented generics.
- The proposed guidelines will create an enormous administrative filing burden for companies with patented generics.
- The proposed guidelines will negatively impact competition in generic sector.
- The proposed guidelines will discourage innovations and negatively impact domestic R&D investments by generic manufacturers.

PMPRB Regulation of Patented Generics will NOT Lower Generic Drug Prices

Regulating the prices of generic medicines in Canada cannot be achieved through the *Patent Act*, simply because most generic medicines are not covered by patents. Patented generic products comprise a minority of generic products and hold no pricing power over non-patented generics. Since the PMPRB can only extend jurisdiction over patented generics, any effort by the PMPRB to control patented generics can have no impact on overall generic pricing in Canada.

Regulation of Patented Generics Inconsistent with Federal Priorities

Imposing the current proposed guidelines and reporting requirements on generic patentees would be inconsistent with the federal government's objectives of streamlining regulation by ensuring that regulatory measures are proportionate to the benefit gained for Canadian citizens and businesses. Indeed, this would hinder competition and create inequalities in Canadian generic business while failing to achieve the policy objective or protecting the interests of consumers. It will also inflict substantial administrative burden on both Board staff and patentees.

It is also important to note that most of the pharmaceutical manufacturing capacity that exists in Canada today is generic, while most brand-name drugs are shipped into Canada. At a time when Canadian manufacturers across are facing unprecedented challenges, the imposition of such unnecessary and highly burdensome regulation on a highly competitive industry is not in the public interest.

Costly Proposals for Canadians

The proposed regulation of patented generic prices in Canada comes at a high price for generic manufacturers, but it will also be costly for Canadians through the expansion of the Board's activities. Regulation at the detailed level proposed by the PMPRB requires resources, not only from companies, but also Board staff. Furthermore, given that generic medicines are below the non-excessive brand prices and comply with provincially regulated maximum prices, Canadians obtain no benefit from this costly regulatory

process applied to a small number of the generic medicines available on the Canadian market.

At a time when all government budgets are being reviewed to identify additional savings and efficiencies, increased spending by the PMPRB to monitor the prices of some generic competitors, which are lower than brand-name drug prices and regulated by provincial governments, runs counter to the fiscal priorities of Canadians. These funds would be much better spent on other more urgent health care priorities that would provide a real benefit to Canadians.

Board Mandate

Generic manufacturers and the Canadian health care system have not benefited from extensions in government sanctioned and enforced market monopolies, which were granted to brand companies in 1987 through Bill C-22 and later strengthened by Bill C-91 and other Regulations under the *Patent Act*.

The PMPRB was created in 1987 to report certain information to Parliament and to ensure prices of patented drugs are not excessive within the context of the *Patent Act* and the objectives of industrial development. Parliament was clear that the Board was established to protect against excessive prices and not prices that some payer believes to be high. There is no indication Parliament suggested the PMPRB could be more effective at price setting than the free market and intended the PMPRB to focus on drugs that had no competitors.

The PMPRB has existed for almost 20 years without jurisdiction over generic drugs. By definition, generics are low-cost multi-source products, and are not sold under a patent monopoly. The PMPRB is now taking an expansive approach to interpreting its mandate with respect to patented drugs. It claims that the *Patent Act* requires all patentees to file and report information on prices, sales and R&D spending. This includes generic products covered by patents that are sold in a competitive, multi-source environment.

This proposed expansion of the PMPRB's mandate ignores the original policy intent of the PMPRB, which was created to ensure monopoly drug prices are not excessive. PMPRB is following an overly simplistic understanding of its role, without regard to cost or the absence of benefit.

The Board's new policy discourages the investment in innovation by generic companies and is contrary to the purpose of the Act. It is well known that more competitors result in lower prices. Price controls applied to generic products will reduce the number of competitors in the market. This is contrary to the Board's stated consumer protection objectives.

The self-expansion of the PMPRB's mandate and the associated increases in the PMPRB budget required for the corresponding expansion of its activities should be of concern to both parliamentarians and federal policy makers.

Pricing of Generic Drug Products in Canada

Drug costs are the fastest rising cost for Canadian governments and for employers that sponsor drug benefit plans for their employees, and it is brand products (not generics) that are driving these cost increases. In fact, large savings have been achieved in the reimbursed price of generic medicines in recent years.

The provinces of Ontario and Quebec have recently made significant changes to the way in which generic drugs are priced in their jurisdictions, which has already generated hundreds of millions of dollars of further cost savings. Other provinces are currently reviewing the methods for determining reimbursement pricing for generic drug products in their jurisdictions.

Generic drugs provide excellent value for Canadians. Even though generic drugs are dispensed by pharmacists to fill more than 50% of all prescriptions in Canada, they account for only 23% of the \$20-billion that Canadians spent on prescription medicines in 2008.

Increasing the use of cost-saving generic medicines is the single most effective way to control drug costs. In Canada, the use of lower-cost generic prescription medicines already saves governments, employers and consumers more than \$3-billion every year. These savings are expected to increase in the coming years as higher utilization rates for generic drug products are achieved.

From the point of market entry, a patented generic will normally become engaged in fierce competition with between 2 and 10 non-patented generics to gain market share. Patented generics and non-patented generics are treated equally under provincial and territorial laws, and all generic manufacturers compete within market frameworks, regulations and laws determined by provincial and territorial governments. No market or price advantage can be obtained by the holder of a generic patent, and no public benefit can be achieved through adding an additional layer of federal price regulation on some generic products.

Maximum allowable generic drug prices in Canada are set by provincial governments. As such, discounts and rebates to pharmacies are the primary focus of market competition in the generic pharmaceutical industry. These programs have no direct impact on retail generic drug prices. Many factors affect the discounts, rebates, allowances and other programs offered by a generic manufacturer in a given year.

These well established practices in the provincial market framework for generic products are documented in two Competition Bureau of Canada reports. Excerpts from the 2007 Report can be found in Appendix B; however, CGPA urges the PMPRB Board and staff to familiarize themselves with both the 2007 and 2008 Competition Bureau reports to gain a better understanding of the complex market frameworks in which generic drug products are sold.

The PMPRB has a legislative obligation to ensure that prices charged for patented medicines are not excessive. Generic products are introduced at a fraction of the pre-generic brand retail price. In this context, it is only reasonable to consider the generic price to be non-excessive. Any PMPRB oversight of patented generic medicines should

recognize the unique challenges to the generic industry, and as such should not subject them to administrative burdens disproportionate to consumer benefit.

The current proposed PMPRB Guidelines for patented generics are out of step with the pricing and market realities for generic drug products. We do not believe the PMPRB brand pricing guidelines have either the certainty or the flexibility to deal with the generic market. The Board's decision also imposes a very large regulatory burden in a low-margin, highly competitive sector.

It is imperative that generic companies be able to respond quickly to market forces such as cost increases in order to survive in a fiercely competitive market. There is no sensible rationale for limiting price increases of patented generic companies, as long as the price remains below the introductory MNE set by the brand price.

CGPA has been unable to identify any legal, administrative or other impediments that would prevent the Board from developing a separate approach to dealing with patented generic drugs, which are sold in highly competitive situations. Price increase restrictions should be excluded for generic manufacturers provided the generic prices remain below the non-excessive brand alternative.

Generic Supply Chain

Generic medicines, like over-the-counter drug products, face competition in both the distribution and consumer markets. The pricing of generic drugs in Canada remains a provincial jurisdiction, and there is fierce competition for market share amongst generic manufacturers once brand patent issues are resolved and generic products are allowed to enter the market. The implication of the PMPRB action is to suggest it can set a price more effectively than can the free and open competitive market. This is completely contrary to the spirit of the law under which the PMPRB has been mandated and any known position taken by Parliament.

Bioequivalent Brand Integral to Generic Approval and Pricing

Generic drugs are identical or bioequivalent to higher-priced brand-name versions in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. The pricing of generic drugs is a provincial jurisdiction in Canada, and maximum reimbursement prices are set as a percentage of the brand-name reference product. As generic drugs are always priced lower than the bioequivalent brand, the price of a patented generic cannot be deemed excessive.

The brand medicine is integral to the approval, marketing and pricing of a generic medicine in Canada.

When a generic drug submission is reviewed, a direct comparison to a brand medicine is made. The product must be identical or "bioequivalent" to the brand medicine in order for the generic product to receive market authorization. In Canada, a generic medicine receives a "Declaration of Bioequivalence" to the brand reference product at the point of approval. In addition, the generic medicine cannot make additional health claims and can only be used as per the approved brand indications.

Generic prices are linked to the bioequivalent brand price in provincial markets across Canada and in many OECD countries. In all cases where generic price linkage is established, the amount of the discount is explicitly defined by the regulator.

As the bioequivalent brand product is central to the approval, marketing and pricing of generic medicines in Canada, it is appropriate to use the Canadian price of bioequivalent brand to determine if the price of the Canadian generic is excessive. The price of the generic in Canada is set based on the equivalent brand in Canada, not foreign prices. Any patents for generic medicines have no impact on these prices. As such, there is no need to look further.

Difficulties with International Price Comparisons of Generics

There is a misconception that the prices of generic medicines in Canada are high compared to other jurisdictions. Published international price comparisons for generic drugs have been incomplete as they typically reflect flawed methodologies and data issues. For example, these studies have often compared the retail generic prices in Canada with the wholesale generic prices in other jurisdictions, which does not provide for an accurate comparison of international prices.

There are many factors that can impact generic pricing in other jurisdictions. These include (but are not limited to):

- Population of the jurisdiction in question
- Strength of the domestic generic and/or brand manufacturing base
- The number of generic players in the market
- The supply chain for generic products
- The prescribing rate for generic drug products
- The interchangeability policies that may exist
- The ability of pharmacies to mark-up the price paid by consumers
- The general nature of system (public, private or mix)

The pricing for generic drug products in PMPRB comparator countries in the European Union is also generally regulated at the national level, which is different than the Canadian system where the price regulation occurs at the provincial level. For detailed information on the pharmaceutical regimes for comparator countries in the European Union, please refer to the Österreichisches Bundesinstitut für Gesundheitswesen report prepared for the European Commission entitled “Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States”, 2006.

CGPA is aware of no other jurisdiction that treats certain players in the generic market differently, even though some generic products have patents in other jurisdictions. It is CGPA’s position that generic manufacturers should be exempt from filing international prices for patented generics. Given the difficulties associated with obtaining an accurate international price comparison for generic drugs, international prices should not be used to set a maximum non-excessive price for the Canadian market.

It remains the view of CGPA that a determination of excessive pricing for patented generics in Canada must be tied to domestic price tests alone. If a generic medicine is priced below the non-excessive price of the brand competitor, the generic price should automatically be deemed to be non-excessive.

While brand-name medicines may be present in all seven comparator countries, it is very likely that a patented generic sold in Canada will not be present in a comparator country. It is very possible that the patented generic medicine will be sold in 0 to 3 of these comparator countries, which will not present an accurate or fair international price comparison for the patented generic.

The Board has not explained how the international price comparison for patented generic in this situation of little to no presence in PMPRB comparator countries, which CGPA expects will be a common occurrence. Again, if the Board is unwilling to exempt patented generics from the HIPC Test, modifying the test to allow for the use of the bioequivalent brand price by a patented generic is the most obvious, most simplistic and most effective solution.

Strong Rationale for Different Generic Guidelines

CGPA and its member companies urge the PMPRB Board to reconsider its decision to take the sound proposals developed by PMPRB staff and CGPA members through the CGPA-PMPRB Working Group.

By definition, generic drugs are low-cost multi-source products. Subjecting patented generics to the brand's monopoly requirements would limit the ability of a patented generic manufacturer to compete against other manufacturers of the same medicine who do not have patents, as the other generics will be free to change prices at will in reaction to the competitive environment.

PMPRB regulation of patented generics is not an effective way to control generic drug prices as all generic products are already regulated by provincial governments to be lower than the non-excessive brand price as regulated by the PMPRB. Regulation of ex-factory prices of patented generic medicines will have no impact on prices paid by consumers.

Generic patented medicines are unique from brand patented medicines in that they operate in a completely different and more competitive environment. There is no known case where a patent held by a generic company resulted in a monopoly or which conveyed pricing power.

Precedent for complaints based regulation has already been established through PMPRB price regulation of veterinary drugs and over-the-counter (OTC) drugs. This would be a more appropriate regulatory environment, in the context of a claim of jurisdiction by PMPRB.

The current proposed PMPRB Guidelines impose a substantial burden on generic medicines, with virtually no benefit to Canadian consumers. This approach is not consistent with the Canadian government's initiatives to encourage domestic R&D investments and avoid unnecessary and inefficient regulation.

Part Three: Specific Comments on Revised Draft Excessive Price Guidelines

The Canadian Generic Pharmaceutical Association and its member companies do not accept that patented generics should be covered by the Board's Excessive Price Guidelines, and the following comments are made without prejudice to this position.

The generic pharmaceutical industry is strongly opposed to the current proposed guidelines, which subject patented generic products to guidelines developed to reflect brand-name pricing realities and are inappropriate for patented generics. If the Board feels it must proceed, it remains the view of CGPA and its member companies that the market realities facing generic products are unique, and separate guidelines are required for patented generic medicines.

Schedule 4: Reasonable Relationship Test

CGPA agrees with the Board's decision that a patented generic be compared to the non-excessive bioequivalent brand price at market entry. This limited therapeutic class comparison reflects a workable proposal developed by the CGPA-PMPRB Working Group. This domestic test reflects the price linkage made by provincial governments between the maximum allowable price for a generic medicine and the non-excessive brand price as monitored by the PMPRB.

Schedule 6: Highest International Price Comparison (HIPC) Test

The HIPC Test is unworkable for patented generics for several reasons:

- Some patented generics will have no international comparators in which the same patented medicines is sold, although the same chemical is likely sold by other patentees.
- Some Canadian patented generics may have the same patent in a few of the PMPRB comparator countries, and possibly in countries with lower list prices for both brand-name and generic drug products.
- In the case of authorized generics, a company would often have no way to know which products are sold under the same patent in other jurisdictions.

The Board has attempted to justify many of its decisions on the basis of fairness. The current HIPC Test is not fair as it places different international comparators on three bioequivalent products – the brand patented medicine, an authorized generic, and an independent patented generic. From a public policy perspective, there is no sound rationale to place three different sets of rules on three identical chemicals.

It is the view of CGPA that the Board does have the legal flexibility to create an international price test using the prices for bioequivalent products, and not rely solely on the "same patent". We remain at a loss to understand why one strength of a chemical should be forced to be lower than another. Patented generics are priced lower than the domestic bioequivalent brand, and are therefore not excessive. Given this reality, there is no compelling reason to force the Board's Excessive Price Guidelines on non-excessively priced generics.

Given the serious inequities associated with the proposed test, we again urge the Board to exempt patented generics from the HIPC test or, at an absolute minimum, implement an international price test using the prices of bioequivalent products.

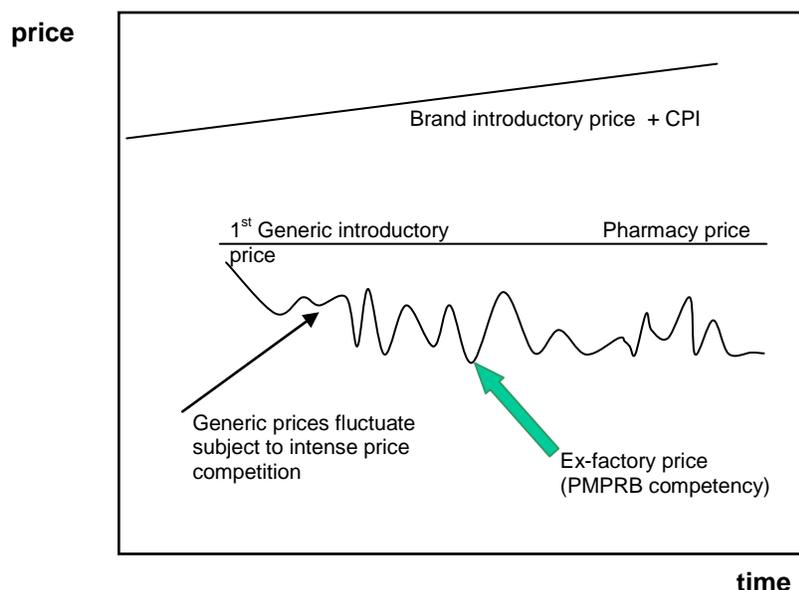
Schedule 9: CPI-Adjustment Methodology

The CPI Test is not appropriately sensitive to the competitive nature of the generic industry as it would hinder price competition. Price competition requires price fluctuation – both increases and decreases. The current guidelines penalize patentees, which lower prices for any reporting period since the return to the original price would exceed the CPI adjustment factor. In effect, ex-factory prices are not allowed to float freely as would be required to facilitate price competition. This is true for both new drugs and existing drugs.

The intention of the *Patent Act* was clearly not to hinder price competition, but to provide limits to the monopoly power created by patents. The current guidelines, however, inhibit ex-factory price competition through its CPI methodology. Ex-factory price volatility is part of a healthy price competition among generic manufacturers and often is the result of contract tendering or contract loss. This volatility has no impact on the prices paid by consumers as the reimbursement prices for generic drug products are set by the provinces.

We believe that there must be the ability to alter prices periodically in the face of market realities and economic conditions as long as these prices remain below the brand price. CGPA believe the Board's application of the CPI methodology must be removed from patented multi-source generic products. This is justified by applying the stated purpose of the CPI methodology to the current context.

Figure 1: Price competition in the generic industry



Although the DIP methodology in Schedule 10 attempts to mitigate the incompatibility of price fluctuation and the Board's CPI methodology as a result of the amount of price fluctuation and number of different agreements involved in the competitive generic environment, this proposal fails to provide any mitigation due to the substantial burden imposed.

Schedule 12: Any Market Price Reviews (New and Existing Drugs)

CGPA believes the any market price reviews for generic drugs will be artificial and meaningless, and will create significant reporting problems for generic manufacturers given the pass-through nature of a generic manufacturer's relationship with a wholesaler. Pharmacy is the primary customer for a generic manufacturer – the wholesaler is not the customer. Appendix A provides an example illustrating the generic supply chain in Canada.

The Any Market Price Reviews are a new addition to the proposed guidelines. It is also CGPA's view that the Board has not demonstrated a sufficient need for such reviews to industry, particularly as they pertain to patented generics. As such, it is CGPA's strong recommendation that the Any Market Price Reviews at introduction and for existing drugs be removed from the final Excessive Price Guidelines.



APPENDIX A

Example: Generic Supply Chain

The following example has been prepared to illustrate the role of the various parties in the generic supply chain in Canada.



Health Canada

- Health Canada receives Abbreviated New Drug Submission (ANDS) from Generic Manufacturer for Medicine X.
- Health Canada reviews submission. Health Canada has a legislative and regulatory requirement to ensure that all generic drugs approved for the Canadian market are identical or bioequivalent to the brand-name version in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.
- Health Canada approves Medicine X for Canadian market and grants it a "Declaration of Bioequivalence".



Manitoba

- Generic Manufacturer applies to provincial governments to have product included on their formulary listings, thus being designated as interchangeable and bioequivalent with the bioequivalent brand name product.
- In this example, the Province of Manitoba has set a maximum reimbursement price for Generic Medicine X at \$1 per unit on its drug formulary.



Generic Manufacturer

- Generic Manufacturer negotiates with Pharmacy Customer to purchase its products. The agreement in this example includes a rebate or professional allowance in the amount of 50 cents per unit for Medicine X.
- Generic Manufacturer distributes Medicine X to Pharmacy Customer through a Wholesaler. Wholesaler is invoiced \$1 per unit by Generic Manufacturer.
- Generic Manufacturer pays rebate or professional allowance of 50 cents per unit of Medicine X directly to Pharmacy Customer. This is typically paid on a monthly basis after sales have been made.



Wholesaler

- Wholesaler receives Medicine X from Generic Manufacturer.
- Wholesaler receives invoice from Generic Manufacturer in the amount of \$1 per unit for Medicine X. No rebate negotiated or received by the Wholesaler. Generic Manufacturer pays a typical distribution fee to Wholesaler in the amount of 5% of list price (5 cents per unit in this example).
- Wholesaler distributes Medicine X to Pharmacy.
- Wholesaler invoices Pharmacy \$1 per unit of Medicine X.



Pharmacy

- Generic Manufacturer's Pharmacy Customer receives Medicine X from Wholesaler.
- Pharmacy receives invoice from Wholesaler in the amount of \$1 per unit of Medicine X.
- Pharmacy Customer receives a professional allowance or rebate of 50 cents per unit of Medicine X directly from the Generic Manufacturer.
- Pharmacy Customer sells Medicine X to Consumer for \$1 per unit (plus any Pharmacy mark-ups and dispensing fees).



Consumer

- Consumer purchases Medicine X from Pharmacy for \$1 per unit (plus any Pharmacy mark-ups and dispensing fees).
- Consumer files for reimbursement of amount paid for Medicine X with insurance provider.



Manitoba

- Province of Manitoba reimburses either consumer or pharmacy \$1 per unit for claimants eligible under its program.

APPENDIX B
Excerpts from Competition Bureau of Canada's
Canadian Generic Drug Sector Study
October 2007

The Canadian Generic Drug Sector Study is the first comprehensive report to outline and describe the competitive framework for prescribed generic drugs in Canada, with a focus on market structure and regulatory features.

CGPA encourages the PMPRB Board of Directors and PMPRB staff to review this document in detail to ensure a better understanding of how generic drug products are sold in Canada. In particular, CGPA wishes to draw the Board and staff's attention to the following aspects of this document:

Role of Generic Drugs

"Generic pharmaceuticals ("generics") play an important role in helping to control prescription drug costs in Canada. Generics are determined by Health Canada to be "bioequivalent" to patented pharmaceuticals. Their role is to provide competition for brand-name products when their patent protection ends." – page 5

Generics and Pharmacy Customers

"In the case of sales to retail pharmacies, pricing decisions by manufacturers consist of two elements: the establishment of the product's invoice price and the net pharmacy price. The net pharmacy price is the price paid by the pharmacy net of any off invoice rebates and discounters. Invoice prices are the amounts typically reimbursed by public and private drug plans. As developed further in section 5.A., limited competition appears to take place in invoice prices. Until recently, invoice prices have tended to reflect maximum generic prices allowed under Ontario legislation. Price competition among manufacturers has tended to take place at the pharmacy level in the form of lower net pharmacy prices. Once generic versions of brand-name products are placed on provincial formularies and are designated as interchangeable, they essentially become commodity products.

"This situation results in pharmacies being the most important and influential customers of generic manufacturers. Traditionally, the most important factor in competing for pharmacies' business, where there are multiple generics available, has been generic manufacturers providing rebates off invoice prices. Rebates on generic drugs are not recorded on invoices, but are provided to pharmacies and hospitals in a separate transaction often as a lump sum for drugs purchased during a given period." – page 17

"The effects of the competition among manufacturers have traditionally not been reflected in invoice prices for generic drugs. Rather, with price competition focused on pharmacies, its effects are reflected in net pharmacy prices." –page 21

"Pharmacies and hospitals provide the main interface between generic drug suppliers, patients and reimbursers. They are the main focal point for competition among generic manufacturers." – page 25

"Retail pharmacies play a pivotal role in the competitive framework for, and pricing of, generic drugs in Canada. Though they do not prescribe pharmaceuticals, after a drug has been prescribed, pharmacists normally have broad scope, under provincial and professional laws, policies and regulations, to substitute among interchangeable generic and brand drug products

when filling prescriptions. As well, to minimize their costs, pharmacies have an interest in stocking only one, or a small number of interchangeable products.

“Because of this, competition among generic manufacturers and suppliers to supply generic drugs to patients in the community has tended to focus on pharmacies. As indicated in the manufacturing chapter, this competition takes place in a variety of ways. An important dimension has been to grant rebates to retail pharmacies off pharmacy invoice prices.

“Previous analysis of the Canadian pharmaceutical sector and testimony provided in recent hearings on amendments to Ontario’s generic drug related legislation and regulations indicate that these rebates provide important returns to pharmacies.

“Rebates have also provided a financial incentive for retail pharmacies to substitute generic products for branded products. As indicated in the manufacturing chapter and discussed further in section 5.A, off invoice rebates and discounts and other such benefits, have normally not been reflected in prices reimbursed by public and private insurers. Rather, those contacted for this study indicated that reimbursed prices for newly introduced generic drugs reflect the former maximum limits under Ontario provincial drug benefit legislation.” – page 28

“However, public sources and information provided by parties interviewed for the study indicate that net pharmacy prices have been, on average, at least 40% below the invoice price, and as much as 80% lower in some cases. These rebates have provided incentives for pharmacies to substitute generic drugs for brand products and have been an important source of income for them. **It may be noted that competition in the form of rebates, by its nature, is not reflected in price studies comparing invoice prices in Canada versus other countries.**” – page 53

Generics and Hospital Customers

“Prices for generic drugs used by hospitals are generally determined by negotiations and contracting between the hospitals themselves and the manufacturers. While this may be done on a hospital by hospital basis, it is increasingly being done through group purchasing organizations (GPOs) or Regional Health Authorities (RHAs). – page 33

“As with retail pharmacies, drugs used by hospitals may be obtained through IPDs [Independent pharmacy distributors]. By streamlining their pharmaceuticals procurement through an IPD, hospitals can benefit from channel efficiencies, reduced inventory and decreased administrative costs.” – page 34

Distribution Role of Wholesalers

“While they play an important intermediary role in the sector, IPDs’ (Independent pharmacy distributors’) impact on the competitive framework and pricing of generic drugs appears to be limited.” – page 23

“While ancillary terms may vary, such as discounts for prompt payment, the price paid by wholesalers for pharmaceuticals is based on the provincial formulary or manufacturers’ list price. In the case of generics, the price to distributors is discounted by the distribution fee (or mark-up) allowing the drugs to be distributed to pharmacies at their invoice price. According to sources, these fees are typically in the range of 5% of the value of generic drugs distributed. **This is not the case with branded products, where distribution fees are typically paid by the pharmacy and are in addition to the drug invoice price.**” – page 23

“Since drug prices are negotiated with the manufacturers, the main point of negotiation with IPDs is their mark-up. Distribution and warehousing services are also negotiated. According to persons contacted for the study, bidding for multiple source generic products can be highly competitive. Rebates off invoice prices are often included in the contract negotiations. In the case of GPOs, manufacturer rebates are sent in a lump sum on a regular basis, usually quarterly, semi-annually or annually.” – page 35

Public Plans

“Public plan maximum formulary price policies require generic drugs to be priced at or below a maximum price relative to their interchangeable branded products.” – page 44

“Net acquisition cost policies that are aimed at capturing the value of rebates and other such benefits potentially allow public plans to increase their benefits from competition among generic manufacturers. However, the monitoring and auditing capabilities of public plans has traditionally focused on pharmacy invoices that do not capture off invoice rebates, discounts and other benefits.” – page 44