Canadian Generic Pharmaceutical Association
412 [illegible]ge Street
Suite 409
Toronto, Ontario
M2P 2B8
Tel: (416) 223-2333
Fax: (416) 223-2425
www.canadiangenerics.ca
E-mail:
info@canadiangenerics.ca



September 28, 2007

Dr. Brien Benoit
Chair
Patented Medicine Prices Review PMPRB
333 Laurier Avenue West, Ste 1400
Box L40, Standard Life Centre
Ottawa, ON K1P 1C1

Re: Regulating Prices of Patented Generic Products

Dear Dr. Benoit:

As promised at our last meeting of September 12, 2007, I am forwarding to you a written proposal for 'Regulating Prices of Patented Generic Products'. The proposal is in two parts:

a) An Executive Summary and
b) Discussion Paper

Our proposal builds on the presentation given by the Canadian Generic Pharmaceutical Association (CGPA) at the September 12 meeting.

The CGPA looks forward to the establishment of a Working Group on Generic Pricing involving the PMPRB and generic drug industry representatives. We recommend that a member of the Board Chair this group.

I look forward to hearing back from you and to working together cooperatively to develop guidelines appropriate for patented generic products.

Yours sincerely,

Jim Keon

Jim Keon
President
CGPA

Enclosures

CGPA

# Regulating Prices of Patented Generic Products

## Executive Summary

This submission to The Patented Medicine Prices Review Board is in respect of ongoing consultations regulating the prices of patented medicines and in particular, the application of Guidelines to patented generic products.

The Canadian Generic Pharmaceutical Association (CGPA) believes that the degree of regulatory oversight must be proportional to the risk faced in manufacturers charging "excessive prices" and that regulation must be constructed to consider the specific business practices of the companies being regulated. There are very significant differences between pricing of branded patented drugs and generic patented drugs, which means the current Guidelines designed specifically for brand manufacturers are not appropriate for generic manufacturers. When the Board was established, it was accepted that a patented product was synonymous to a monopoly product. In this submission we are dealing with patented multisource products.

The following should be considered in developing Guidelines for patented generic products:

Very few generic products have patents and the types of patents held by generic companies do not hamper price competition. Typically, only one of several manufacturers selling a particular generic product is a patentee. This means Guidelines would apply to only one of several manufacturers of any generic drug.

Prices and price increases of generic copies are regulated by provincial legislation, regulations or policy (depending on the province). These regulations dictate the generic must be sold at a per unit price lower than the equivalent brand product. If the brand product has been found to be "not excessive", logic dictates the lower priced generic must also be "not excessive".

Generic company net prices or "transaction" prices are lower than those listed in provincial formularies or reported by data suppliers. The perception that there are higher generic prices in Canada than in the US has been based on misleading information.

PMPRB CPI-Adjustment Guidelines will interfere with the normal course of business of generic manufacturers since transaction prices in any highly price competitive market will rise and fall. Generic transaction prices will rise and fall even when consumer prices remain constant. The existing Guideline will cause continual investigations and will discourage price competition. This regulatory initiative will have no effect on prices paid by consumers.

There is precedent for specific regulatory measures applying to a market segment or classes of drugs as demonstrated by the way patented veterinary and OTC drugs are dealt with by the PMPRB or the different rules applied to categories of drugs.

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CGPA proposes effective Guidelines applicable to generic copies. These guidelines are designed to limit the regulatory burden on manufacturers and Board Staff, while protecting consumers from excessive generic prices and minimizing the chance of hearings for products already selling at a fraction of existing Brand prices.

Recommendations

The proposed guidelines deviate only minimally from the current Guidelines so as to maintain some consistency, while not inhibiting price competition at the ex-factory level. Key elements include:

1. Identification by generic manufacturer that its patented product falls under the definition of a patented generic as outlined in the proposed guidelines.
2. Application of the Reasonable Relationship price test to the existing Brand, or if the product is discontinued, to the last available formulary price for that brand plus CPI.
3. Application of existing international price comparison, using international Brand formulary prices.
4. Removal of CPI methodology for patented generic products to avoid mix shift effect and allow generic manufacturers to compete on price at the ex-factory level.
5. Regular filing of price information and full data filing for patented generic products under certain conditions.

These measures outlined in the proposed guidelines would help to balance the Board's regulatory obligations with the market realities of a price competitive industry.

Since it is clear there are significant problems in applying the existing Guidelines to patented generic products, the CGPA would like to recommend the Board instruct PMPRB staff to halt any investigations into pricing of generic products until after revised Guidelines have been established. It is a waste of both patentee and PMPRB resources to conduct this work based on Guidelines that we trust will change substantially.

Next Steps

The Board has proposed the establishment of a Working Group on Generic Pricing. CGPA wholeheartedly supports this as a means to quickly develop reasonable Guidelines applicable to patented generic drugs. A major part of the Board's responsibility is for policy development and the creation of appropriate Guidelines. The original Guidelines and amendments over the past 15 years were formulated with direct and active participation of Board members. We recommend a member of the Board chair this group.

We suggest the agenda for the Working Group could include the preparation of any analysis the Board requires to be satisfied CGPA's position is accurate, to review and modify the proposed Guidelines proposed above, identify any gaps in the proposed Guidelines and develop the appropriate public communications documents.

Draft

Discussion Paper

# Regulating Prices of Patented Generic Products

**Purpose**

The purpose of this document is to suggest a policy and Guidelines to amend the Patented Medicine Prices Review Board's (PMPRB) Excessive Price Guidelines related to patented generic products. In keeping with the Board's current Guideline review, these proposed guidelines have been drafted with regard to the excessive price factors outlined in section 85 of the Patent Act. This document and the proposed Guidelines are designed to inform the Board of the facts and to enter into a dialogue with the Board that will result in a sustainable long-term solution to pricing Guidelines applicable to patented generic products.

**Background**

In May 2006, the PMPRB began an extensive review of its Excessive Price Guidelines (Guidelines). The primary purpose of this review was to obtain stakeholder feedback concerning specific elements of the Guidelines and to ensure consistency between those Guidelines and excessive price factors outlined in Section 85 of the Patent Act[1]. As highlighted in the recent Dovobet case, the Board considers its Guidelines an articulation of the methodology used in applying the factors in the Patent Act[2]. Through its Guidelines, the Board provides transparent and predictable guidance to patentees on the approach used by Board Staff when determining whether prices of patented medicines are excessive[3].

Board members continue to meet with stakeholders including the Canadian Generic Pharmaceutical Association (CGPA) on issues related to the practical application of the Guidelines and are gathering feedback to guide future direction. It has become clear that the current Guidelines were not designed to consider the regulation of patented products that are subject to price competition at the ex-factory level (generic drugs with tangential patents). CGPA and its member companies believe the Board's current Guidelines are not in the public interest and are not appropriate for such products. The reasons for this were discussed and detailed in a meeting between the Generic Industry (CGPA and its members) and the Board on August 22, 2007.

There was general agreement at the meeting that the generic and brand industries are of sufficient difference to warrant separate treatment under the PMPRB's Excessive Price Guidelines. Board members expressed interest in new policies and Guidelines, which would apply to drugs in a competitive pricing environment and invited the generic industry to a bilateral consultation meeting on September 12, 2007.

This document discusses issues related to the application of the current guidelines to this specific group of products, and proposes a new direction for their management

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[1] Excessive Price Guideline Discussion Guide, May 2006.
[2] Decesion:PMPRB-04-D2-Dovobet, April 19, 2006
[3] Excessive Price Guideline Discussion Guide, May 2006.

under the PMPRB's Excessive Price Guidelines. CGPA has drafted a proposed set of guidelines, which better balance the need for regulation with the market realities of a price competitive industry.

The policy direction proposed by CGPA is consistent with the Federal Government's current direction with respect to the regulation of competitive industries. As demonstrated by recent Cabinet direction on CRTC regulations, the Government believes that market forces and competition should be allowed to the greatest extent possible and regulation should be used only when necessary[4]:

> "In exercising its powers and performing its duties under the Telecommunications Act, the Canadian Radio-television and Telecommunications Commission (the "Commission") shall implement the Canadian telecommunications policy objectives set out in section 7 of that Act, in accordance with the following:
>
> (a) the Commission should
>
> (i) rely on market forces to the maximum extent feasible as the means of achieving the telecommunications policy objectives, and
>
> (ii) when relying on regulation, use measures that are efficient and proportionate to their purpose and that interfere with the operation of competitive market forces to the minimum extent necessary to meet the policy objectives;"

These directives to the CRTC are a reflection of the Government's general philosophy on government regulation of competitive industries:

> "Canada's New Government believes that reliance on market forces and competition benefits Canadian businesses and consumers...In a competitive sector, there is no reason to prevent consumers from getting the best offers" – Former Industry Minister Maxim Bernier

The generic pharmaceutical sector competes on price. The current PMPRB Guidelines did not contemplate the regulation of prices of products under direct price competition and as a result, do not serve the Board's objectives or the public interest. They are also not consistent with the Government's direction with respect to the regulation of competitive industry sectors and particularly, in allowing consumers to get the best offer.

Prices among generic competitors at the consumer level are highly regulated by provinces. It is therefore practical for the PMPRB to balance its regulatory intervention in this market segment with this reality.

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[4] http://canadagazette.gc.ca/partII/2006/20061227/html/sor355-e.html

## Same Drug, Different Pricing

Generic drug manufacturers sell products that are already being sold by brand manufacturers. The same very high quality standards are applied by Health Canada to both industry sectors and there are other similarities. However, when it comes to marketing, sales and pricing, these two sectors could not be more different. There is no rational argument that the two industry sectors bear sufficient resemblance in the realm of ex-factory pricing to support identical treatment by the PMPRB.

In this document, generic products mean drugs for which there is substantial and direct price competition among unrelated parties[5]. The average transaction price means the price between the manufacturer and first buyer after deductions for professional allowances, free goods, discounts, rebates and other promotional activities. This is the level of trade for which the PMPRB has jurisdiction. These are not reimbursement prices paid to pharmacies by provincial governments or other payers. Brand drugs refers to products that have monopoly powers over the chemical entity due to the existence of a patent or patents that prohibit other manufactures from producing and selling the same chemical entity. CGPA realizes not all brand products have monopoly pricing powers but this document is restricted to products manufactured and distributed by its members and this gross distinction will be made for ease of discussion.

Brand companies typically make a pricing decision at the introduction of a new product considering many variables. Marketing and sales efforts are directed to market access, (e.g. formulary listings) physician education and other forms of promotion to prescribers. (There may be price competition for hospital business.) For brand products, ex-factory prices to wholesale or retail trade levels generally change by no more than the rate of inflation and infrequently, rising and falling over the space of a few years. The price paid by drug plans and consumers are virtually identical to ex-factory transaction prices.

Generic companies operate quite differently. Generic prices are required to be below those of the brand equivalents according to provincial drug plan rules and the economic reality of the market place. Unlike brand manufacturers, generic manufacturers compete for acceptance by individual pharmacies and pharmacy chains. This competition is based on service levels, breadth of product line and, primarily, ex-factory prices. As a result, average transaction prices are not stable, even for short periods of time, rising and falling as competition demands and market conditions dictate. Actual transaction prices are closely guarded secrets since there is considerable advantage in knowing competitors actual pricing. As noted in the recent Competition Bureau study, ex-factory prices do not bear any resemblance to prices paid by drug plans or consumers. The document also clearly describes the level of price competition among generic manufacturers. We would add that the basic nature of price competition means rising and falling average transaction prices at the ex-factory level.

> Page 20 of the draft Competition Bureau report notes: "The effects of the competition that takes place among manufacturers have traditionally not been reflected in invoice prices for generic drugs. Rather, with price competition being focused on pharmacies, its effects are reflected in the net pharmacy prices. As indicated above, these prices, prior to recent changes in Ontario generic drug legislation, have been estimated to be on average 40% or more below the invoice prices used by the PMPRB and other pricing studies."

[5] There may be instances where a generic is alone in the market as a result of other competitors ceasing to sell the product. This exception will need to be dealt with separately.

Another very major difference between the sectors is that the patents applying to the generic products do not affect the entry of other competitors. Basic patents held by brand companies are intended to restrict competition and can convey pricing power to the patent holder.

Asymmetrical Regulation

Although the actual number has not been determined, very few generic drugs are patented. In some cases, a generic product has a patent because it is licensed from a foreign producer. In others, the patent is on a manufacturing or formulation process, which may or may not be used. In any case, these patents do not impede competition nor do they give the patentee any control over pricing.

The existence of a patent held (or licensed) by one generic manufacturer on a specific drug does not extend patent protection to other generic competitors of that specific drug. In other words, the PMPRB will be imposing a regulatory burden on the company holding the patent or patents but not on other direct competitors selling the same drug which do not hold patents on the drug. This will result in the uneven application of price regulation since only the patented version is subject to the PMPRB Guidelines.

In addition to the inherent unfairness of this situation, this could actually reduce the number of competitors. Smaller companies who tend to license in products may be unwilling to license in otherwise viable competing products due to the filing and other requirements that would be placed on them. In other cases, if the patented generic is required to lower its price below an acceptable level due to the PMPRB Guidelines, it could cease selling the product, leaving the remaining unpatented competitors to continue selling at the higher price (although this would still be at a price lower than the equivalent brand product).

These patents held by generic manufacturers are generally on manufacturing processes or formulations that give these companies an advantage in the highly competitive international market. The Canadian price rules however, may discourage the investment in developing more efficient processes and hamper Canadian-based companies in competing globally. While it is not part of the direct mandate of the PMPRB, the fact the PMPRB was created as part of an industrial development initiative and is within the Patent Act, suggests strongly that this is a factor that the Board must consider.

The actual transaction prices are highly confidential and very sensitive in this extremely competitive market. The patentee data must not be disclosed in any form since there will likely be only one generic company with a patent on a particular drug and any disclosure automatically reveals the pricing policy of a single company. The disclosure of actual pricing practices could seriously jeopardize the competitive position of the patented generic companies.

It is therefore necessary for the PMPRB to consider carefully how any data collected from patented generics is disclosed. It is the position of CGPA that any and all transaction prices must remain confidential and not be disclosed in any form, including during discussions with provinces, in research reports or any other communication.

## In Support of an Alternative Approach

As discussed during the August 22nd meeting, the PMPRB's current price Guidelines are not an appropriate regulatory mechanism for patented generic products:

a. the Guidelines were designed to regulate state granted monopolies created by patents;
b. the generic industry was not part of the price Guideline development;
c. the Guidelines are not appropriately sensitive to the competitive nature of the generic industry (CPI methodology would hinder price competition) as 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 generic 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 Consumer Price Index methodology.

To illustrate potential problems consider the following example:

| | Brand Price | Generic ATP (per mg) | Maximum non-excessive price (MNE) | Excess | Cumulative (500 000 units) |
|---|---|---|---|---|---|
| 2001 | 1.00 | 0.50 | 0.50 | * | |
| 2002 | 1.01 | 0.50 | 0.50 | * | |
| 2003 | 1.02 | 0.35 | 0.50 | * | ($75,000.00 added cost savings to customer) |
| 2004 | 1.03 | 0.50 | 0.35 | $ 0.15 | $ 75,000.00 |
| 2005 | 1.04 | 0.50 | 0.37 | $ 0.13 | $ 140,000.00 |
| 2006 | 1.05 | 0.50 | 0.39 | $ 0.21 | $ 245,000.00 |

In this example:

- The generic price is lower than the brand price in each period;
- The generic company wins large contract in 2003 based on price competition and its average transaction price drops from .50 to .35. Customers realize cost savings in 2003,
- As a result of the CPI methodology, the allowable price for 2004 (MNE) drops (to .35 in this example) and would only be allowed to rise at the rate of inflation;
- The patented generic loses the contract in 2004 and its actual transaction price rises to its previous level. This would be deemed to be "excessive" under current Guidelines;
- The company is liable for $245,000 in "Excessive prices" in coming years (given a small product: 500 000 units); a larger product would increase liabilities exponentially.

- Therefore there is no incentive to lower prices given future consequences.
- Throughout the example, the price of the generic is a fraction of the brand price. Customers are better off with price fluctuations.

The example illustrates the potential problems with applying the current Guidelines to a price competitive industry.

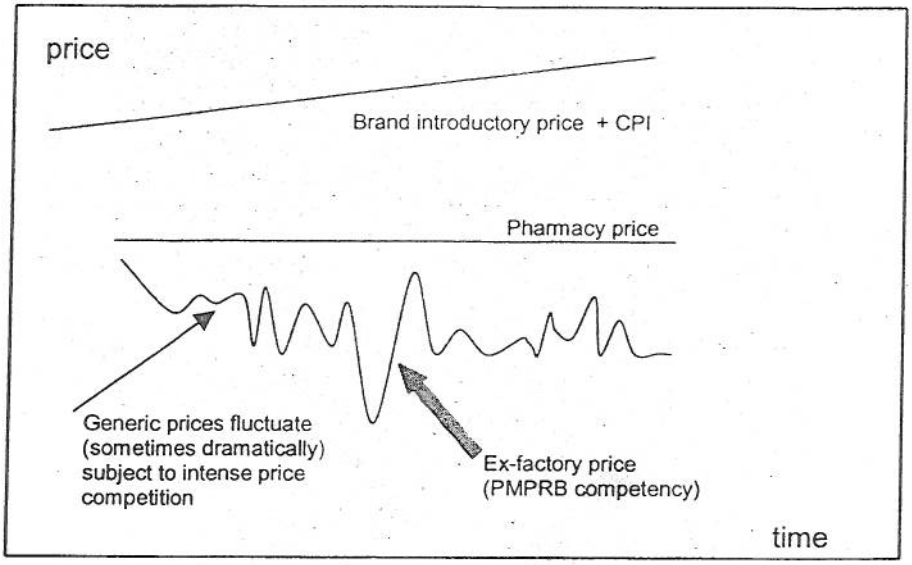
This applies equally to introductory prices of patented generic products. Upon introduction of a generic product, the manufacturer must compete with other already established manufacturers. In order to get pharmacists and others to purchase their product, there may have to be substantially lower prices than the existing products until the new manufacturer gains formulary listing or has made sufficient market inroads. These introductory prices may not be sustainable at the low level. For a first time generic, the problem is compounded by the fact there is no formulary listing for a period of time and incentives must be provided for pharmacies to dispense the generic product. Again, these incentives are not sustainable over the longer term and prices may have to be adjusted upward or incentives reduced.

In addition, generic manufacturers tend to sell at prices that are closer to production costs than do most brand companies. Fluctuations in raw material costs, production scale and other input costs therefore have a direct and immediate impact on generic companies. This means there are more frequent changes in pricing, all of which could trigger investigations under the CPI-Adjustment Guidelines. This also means the PMPRB will have to include the "cost of making and marketing" factor in more investigations. This is notoriously difficult and very time consuming on both parties.

Figure 1 illustrates the current landscape for generic competition. Note that the ex-factory price fluctuates with some volatility, but this is not true for the pharmacy (consumer) price. Such volatility is part of a healthy price competition among generic manufacturers and often is the result of contract tendering or contract loss. The troughs of the ex-factory price line represent low prices offered by generic manufactures to pharmacy as part of the tendering process. The peaks represent prices after the loss of a contract. Note that the pharmacy price remains constant.

We believe that there must also 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. This is with the provision the generic price continues to be lower than what consumers would have paid in the absence of the generic products.

Figure 1: Price competition in the generic industry




Due to the unintended consequence of the current CPI methodology, and the lack of a coherent policy purpose in applying CPI in relation to patented generic products, the proposed guidelines eliminate the CPI component for these products (see ANNEX section on '*Existing Products*') and allow ex-factory prices to fluctuate (as in figure 1) under price competition.

*Mix Shift Price Effect*

Manufacturers, both brand and generic, sell to various levels of trade (retail, wholesalers, hospitals, clinics and others). For a variety of reasons, net ex-factory prices may differ between levels of trade (e.g. retail and hospitals), among different customers within a level of trade and over time. As noted elsewhere, contracts to large buyers may result in lower net ex-factory prices for the duration of the contract. The effect of these arrangements means the average net ex-factory price of a given product will fluctuate sharply in the short term. The degree of fluctuation will depend on the price differences and the volume of contract sales (at the lower price) is as a proportion of total sales of the drug

| Time Period | Proportion of discounted sales | Discounted Price | Net ex-factory price |
|---|---|---|---|
| Time 1 | 20% | 80 | 96 |
| Time 2 (loss of contract sales) | 0% | 80 | 100 |

In the above example, there is a 4% increase in the net ex-factory price despite the fact there has been no price increase. Among generic manufacturers, the contract process and the accompanying price discounting is a continual event. The application of current Guidelines will result in a continual state of investigations resulting in extraordinary costs placed on generic companies. There is absolutely no supportable logic that would suggest the Board should proceed against a patentee for which the transaction price has increased only because it lost some portion of its business.

The application of the current CPI Guidelines means that companies are found to have excessive prices simply due to the winning and losing of contracts. This is contrary to any public policy that is concerned about consumer welfare. There is a clear disincentive to engage in temporary price discounts and this clearly results in an unfair application of the factors laid out in the Patent Act. Changes must be made to the Guidelines to prevent its unjust application in the future and before any further enforcement action is taken by the PMPRB staff. There are currently an unknown number of investigations being undertaken by staff that would be made irrelevant by revisions to the Guidelines.

Special Circumstances

This document has and will concentrate on the normal pattern of generic pricing and the bulk of patented generic products as the situation is understood today. However, this does not deal with the special case of drugs which are at the end of their life cycle. In these situations, many years after the introduction of the drug, there may be only one producer continuing to sell the drug, often a generic manufacturer. In these cases there is no brand price to compare to the sales are very small and the price changes may seem inordinately large.

CGPA suggests that this issue be dealt with at a later date and once the magnitude of the issue is known. However, we wish to make the Board aware of such special cases and that this could require special action.

## Proposed Policy and Guideline Refinements

### Policy Principles for Patented Generic Drugs

In proposing a policy aimed at products in a price competitive environment, CGPA has considered the fact that Board has the authority to discriminate among classes of drugs in the application of the factors listed in the Act and to weigh these factors differently. This is demonstrated by the treatment of both OTC and Veterinary drugs as well as in the way the factors are applied to drugs in each of the three categories described in the Guidelines.

> The intent of the Act was to regulate drugs that are sold as monopolies because of patents, and not drugs that are sold at prices that are already low in a competitive market.
>
> Where the generic price is lower than the brand, and the brand price is not excessive, the generic price must therefore also be not excessive.
>
> Controlling price fluctuations in a competitive market is counter-productive in protecting consumer interests. This only compels a manufacturer to not offer lower prices, either at introduction or during the products lifetime.
>
> The need for regulatory oversight is lessened for generic prices since they are already heavily regulated by provincial governments. Virtually all provinces control the price at which the generic product will be paid and price increases must be fully justified.
>
> The regulatory burden should be kept to an absolute minimum, which includes de minimus data filing requirements.

The proposed guidelines have been designed with careful regard to the excessive price factors outlined in the Patent Act, with considerably less focus on 85 (1)(d) changes in the consumer price index and a larger reliance on the [85 (1)(d)] prices at which the existing brand medicine has been sold in the relevant market. These proposed guidelines fully consider the interests of consumers in ensuring generic prices remain lower than their brand counterparts.

### Product Definition

For the purpose of the proposed guidelines, the relevant products are those which have direct and meaningful price competition and to which a patent applies[6]." This would include products which have been listed as interchangeable by any provincial formulary but exclude line extensions or modified products that do not face price competition. For example, a modified release product sold by the same brand company as the original immediate release product would not qualify.

The definition and criteria are sufficiently narrow to limit the application of the proposed guidelines to generic products in price competitive markets. It is not intended to cover Brand products with no competitors, licensed generics without other generic competitors, or modified release formulations. CGPA recognizes the importance of limiting this

[6] See ANNEX for proposed Guidelines

definition to patented generic products under current discussion and is therefore interested in working with the Board to further refine this definition if necessary.

## Guideline Elements

*International Price Comparison*

Under the proposed guidelines, patented generic products meeting the definition are compared to international prices. This is in keeping with a primary function of the PMPRB to ensure Canadian Prices of patented drugs do not exceed prices for those products internationally. While it is not practical or feasible to require generic companies to report on generic international prices (this information is not available to generic companies for all competitor products sold abroad), it is proposed that Board Staff compare the international formulary prices of the brand equivalent using the existing methodology.

Rationale for this approach:

- Generics do not have access to international pricing data nor do they always market products in international locations
- Sourcing reliable international generic pricing data would result in a financial and regulatory burden for smaller manufactures and Board Staff
- International formulary prices of the brand would provide an upper limit to ensure prices are not excessive.

*Reasonable Relationship to Brand*

The Patent Act factors require that new drug products be priced with consideration given to the prices at which the medicine has been sold in the relevant market. Under the current Guidelines, the two primary tests for new products are the therapeutic class comparison (TCC commonly for category 3 products) and the reasonable relationship test (RR commonly for category 1 line extensions). In the case of the TCC, the highest available comparator caps the allowable price for the new drug. In the case of the RR, the new product cannot be priced at a premium to existing products. Therefore, in both cases the highest available comparator caps the allowable price for the new product.

It is proposed that the Guidelines for patented generic products follow the same principle by ensuring the price of a new generic product is reasonably related to the existing brand product of the same dosage form and strength. Thus CGPA feels the maximum non-excessive price for a patented generic be determined by using the Guidelines existing reasonable relationship test; effectively tying the generic price to the last available Brand price.

In the spirit of limiting regulatory burden, this could be done as described above through a simple identification form to be filed by the generic company. Because the generic price is always lower than the brand price, it cannot be considered excessive relative to its branded therapeutic equivalent. There is little sense in comparing a generic product to other generic competitors because these products are always in a state of flux due to price competition and tendering. Additionally, not all of these products would have applicable patents raising the problem of asymmetric regulation. If a benchmark price was forced to the level of an existing generic competitor this would also interfere with the price competitive ex-factory market.

Provisions are made in the proposed guidelines for situations where the Brand product exits the market following patent expiry. In such cases the "last available list price (or formulary price) for that product plus CPI since the last price increase of that brand product will be used to establish the reasonable relationship price[7]." Thus, there would never be a situation where the existing Therapeutic Class Comparison would apply to a patented generic. There is some trepidation in dealing with this special situation. If all but one generic firm has ceased selling a medicine, it is likely that production and other costs are far different now than when the competitors were in the market. As noted earlier, this situation may have to be revisited to ensure price regulations do not force the last product out of the Canadian market.

## Consumer Price Index

*Proposed Guidelines*

The proposed guidelines would terminate the use of the CPI methodology to patented generic products (those products defined in the *Product Definition* section). This is justified by applying the stated purpose of the CPI methodology to the current context.

*Current Guidelines*

Schedule 4 of the Guidelines details the Current CPI-adjustment methodology:

> 1.1 The price of an existing drug product during the year under review will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted for the cumulative change in the Consumer Price Index (CPI) from the benchmark year to the year under review (CPI- adjusted price).
>
> 1.2 In addition, one year price increases may not exceed 1.5 times the forecast change in the annual CPI.
>
> 1.3 In periods of high inflation (over 10%), the limit will be five percentage points more than the forecast change in the annual CPI

In May 2007, the Board issued a Stakeholder Communiqué regarding the current status of the excessive guideline review process. That Communiqué made specific mention of an issue raised by stakeholders regarding the unintended effects of the Board's CPI methodology. In response to these concerns: "the Board will be drafting language to permit some flexibility in applying the existing CPI methodology for comment by stakeholders[8]." While this issue relates specifically to circumstances where the MNE price calculated for the year under review is less than or equal to the average transaction price (ATP) of the previous year, it is a related example of the need for flexibility.

The above methodology was created in part to ensure that drug prices increased with inflation over time, and to protect consumers from large one-year price increases. This is supported in Board publications from the early 1990's, where the CPI methodology was under review.

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[7] Proposed guidelines (ANNEX)
[8] PMPRB Stakeholder communiqué – May 31, 2007.

Changes leading to the current CPI methodology were discussed and announced in PMRPB's bulletin #9 (October 1992), #11 (July 1993), and #12 (September 1993). At that time the proposed rational for increased Board oversight was to protect consumers from large one year price increases while having minimal impact on patentees:

> "While the present standard provides for pricing flexibility for patentees and protects consumers over time, it may not protect consumers from experiencing price increases in a given year which exceed the current inflationary conditions as measured by the CPI. Moreover, it is evident that the potential for inappropriate one year price increases will exacerbate over time.....over time patentees would be able to make large price increases in one year if prices had not changed or had declined in the past.....The advantage of a one year price test is that it would relate price increases of patented drug products to the current rate of inflation as measured by the CPI. This would further assist consumers in understanding drug prices because of the specific and uniform pricing period for all drugs... This proposal would not have a significant impact upon patentees[9]."

While the proposed amendments in Bulletin #9 (quoted above) were amended in Bulletins #11 and #12 to reflect the direction of the working group tasked to evaluate proposed changes, the purpose and rationale were consistent. The primary purpose (as reportedly endorsed by industry, provincial governments and others) was twofold: 1) prices should not increase more than CPI over time, and 2) to protect consumers from large one year price increases[10].

Despite these intentions, the CPI methodology has unintended consequences with respect to patented generic products. Namely, the methodology:

- inhibits the flexibility necessary for ex-factory price competition;
- creates regulatory asymmetries (only some generic competitors have applicable patents);
- potentially discourages market entrants who have tangential process patents;
- perhaps most importantly, removes incentive for short-term price reductions or low, albeit unsustainable, introductory prices.

1. *Concern: Prices should not increase more then CPI over time*

   <u>The context for unwarranted generic price increases simply does not exist within the Canada regulatory and reimbursement landscape.</u>

   - <u>Generic prices are low</u>: Generic prices in the Ontario Drug Benefit Program average about 49% of the corresponding brand prices based on a comparison of formulary prices for drugs representing about two-thirds of the ODB generic purchases.
   - Transaction prices for these products are even lower. - as noted in the Competition Bureau study, actual transaction prices estimated to be 40% or more below formulary prices.
   - Provincial regulatory and legislative measures will keep consumer prices low:
     - Quebec: Reimbursement prices for generic pharmaceutical products will be governed by 60/54 pricing formula (first generic product listed on government's drug plan formulary is set at 60% of price of

[9] PMPRB Bulletin #9 October 1992 (p.8&9)
[10] PMPRB Bulletin #11 July 1993 (P.5)

equivalent brand-name product, and price of subsequent generics set at 54% of brand price) NOTE: Quebec is also maintaining its Best Available Price (BAP) policy, so most prices will drop to 50% as in Ontario.

- "Professional allowances" for direct patient care initiatives only (5 categories) and limited to 20% in both private and public sector market.
- Ontario: Reimbursement prices for generic products listed on Ontario Drug Benefit (ODB) formulary reduced to 50% of equivalent brand (with some exceptions). This does not apply to the private sector market
- Professional allowances for specific patient care initiatives are limited to 20% of sales in ODB market – unlimited in private sector market.

2. *Concern: Protect consumers from large one year price increases*

Consumer prices are stable in the generic market.

- Competition keeps ex-factory prices low but volatile; however the consumer does not experience most of this price volatility. Consumers are affected by the pharmacy price, which the Board does not have a mandate to regulate. Provinces control formulary list prices and price increases.
- Large one year increases may be an issue but if they have been preceded by low or decreasing prices then the consumer is better off than continually higher prices. Limiting rising prices after a period of falling prices should not constitute "excessive pricing".
- Consumer prices (pharmacy price) are not affected by competition in the ex-factory market unless pharmacy passes those savings (created by ex-factory price competition) along to the consumer.
- Pharmacies have argued that discounting, contracting at lower prices and other business practices are beneficial to the public interest[11]. It does appear that the practice of discounting to pharmacies has contributed to lower dispensing fees, a greater range of services and the sustainability of pharmacies in rural locations.

***Data Filing***

It is proposed that patentees of a patented generic product file the list prices and each formulary price for its patented products and the comparable brand product for each 6 month period specified in the Regulations.

Actual sales data net of rebates, discounts and other considerations would be filed when the PMPRB identified certain conditions. The conditions would be if the Board Staff found a provincial formulary price exceeded the international maximum price of the equivalent brand product or if the generic price listed in a Canadian provincial formulary exceeded the listed price of the equivalent brand product. The price review would be

[11] Various pharmacy representatives: Ontario Standing Committee on Social Policy hearings on Bill 102 -- May 29, 30 and June 5,6
www.ontla.on.ca/web/committee-proceedings/committee_transcripts.do?ParlCommID=7430&locale=en

conducted on actual transaction prices of the generic version versus the list (or formulary) prices of the equivalent brand product.

CGPA would like to reiterate that transaction prices are highly sensitive competitive information. The generic patentee could suffer serious damage should this information become known to competitors. This information should be used only in the course of investigations and not for analysis or in any communication with any party outside of the PMPRB. As a result of this sensitivity, as well as minimizing both staff and patented costs, there is no reason to have generic companies file transaction data every 6 months.

**Conclusion**

The generic pharmaceutical sector is substantially different than the Brand sector and warrants treatment as such under the PMPRB's Excessive Price Guidelines. Generic companies file process patents that are only tangentially related to their marketed products and these patents do not infer market power. Generic manufacturers compete on price at the ex-factory level and pricing flexibility is a vital part of this competition. Despite the fact that generic prices are usually a fraction of their corresponding Brands, PMPRB Staff have recently undertaken an aggressive enforcement campaign targeting generic products. This campaign is likely to cause significant market disruption and result in several lengthy and complex hearings.

CGPA wishes to avoid this scenario and appreciates the opportunity meet with Board Members to discuss a more balanced approach for patented generics.

CGPA's primary issues with the current Guidelines stem from the application of the CPI methodology. Application of this methodology would inhibit the flexibility necessary for ex-factory price competition, create regulatory asymmetries, penalize manufacturers for mix-shift effects, pose a potential barrier to market entry, and remove incentive to lower prices. CPI is therefore the primary target for change in CGPA's proposed Guidelines for patented generics.

The proposed Guidelines represent the direction favoured by CGPA and are intended to be a starting point for further discussion. The Guidelines deviate only minimally from the current Guidelines so as to maintain some consistency, while not inhibiting price competition at the ex-factory level. They are designed to minimize regulatory burden on manufactures and Board Staff.

As the current Guidelines are not appropriate for patented generics, CGPA request that Board Staff halt further enforcement action until suitable Guidelines are established.

ANNEX

# PRICE GUIDELINES FOR PRICE COMPETITIVE PRODUCTS

## Drug Definition

These proposed Guidelines will apply to products that have direct and meaningful price competition and to which a patent applies. These Guidelines apply to products meeting the following criteria:

Have the same active ingredients in the same or similar dosage form and strength to an original product already sold in Canada, either currently or in the past;

Approved by Health Canada as bioequivalent to an existing drug product;

Have been defined to be interchangeable with an existing drug product by any provincial drug plan in Canada or have had products from competing manufacturers listed as interchangeable to them; and

Are not simply a modified release product marketed by the brand company.

## New Generic Products

*International Price Comparison*

The price comparison will be between the average transaction prices of the genericized product and prices of the original product as listed in the government formularies of the countries listed in the applicable Regulations. For the US, the comparison will be to the list prices and FSS prices of applicable original product.

A product meeting the above criteria will be deemed to be not excessive if its average transaction price is lower than the median of the publicly available ex-factory list prices of the equivalent brand product in the seven countries listed in the Regulations.

Reasonable Relationship

The price per unit of the final dosage form (tablet, capsule, etc.) of new generic product must not exceed the per unit price of the original brand product at the time of introduction of the generic product. The initial test will compare the formulary price of the generic to the formulary price brand product. The determination of excessive price will be based on the average transaction price of the generic product and the formulary or list price of the brand product at the same level of trade.

In cases where the original brand product is no longer sold in Canada, the last available list price (or formulary price) for that product plus CPI since the last price increase of that brand product will be used to establish reasonable relationship price.

## Existing Products

*International Price Comparison*

The new Guidelines will adopt the existing Guidelines. The PMPRB staff will monitor the formulary prices versus the international prices of the brand product. If the formulary price of the generic product exceeds the equivalent brand price in the highest priced country, the staff will request the actual transaction data for the generic product. The prices used in the comparison are those defined above. That is, the transaction price of the generic product must remain no higher than the highest international ex-factory list price of the original brand product. The latter prices are those shown in foreign formularies or ex-factory list prices as currently described in Regulations and Guidelines.

*Consumer Price Index Test*

This provision of the Patent Act cannot reasonably be applied to products having direct and active price competition.

## Price Monitoring

For generic products, the PMPRB staff will monitor the formulary list price of new and existing generic products as submitted by the generic patentee. An investigation will be triggered if the Canadian price of the generic product exceeds the maximum international price of the equivalent brand product or the formulary price of the brand product. In an investigation, the basis of comparison will be the transaction price of the generic product and the higher of the formulary or ex-factory list price of the brand equivalent.

## Data Filing Requirements

Generic patentees will file formulary prices for each province for its patented products and the prices of the equivalent brands each 6 months. Ontario Drug Benefit list prices will be used as a "first source" for Board Staff to verify formulary list prices. Transaction data will be required if the formulary list price of a new generic product exceeds the international maximum price of the original product (based on a comparison of publicly available list prices) or the formulary price of the equivalent brand product. The generic company will be obligated to file the actual transaction data within 60 days of the request by the PMPRB staff.

September 2007