GENERIC DRUGS.

CGPA

SAME QUALITY. LOWER PRICE.

October 6, 2008

Dr. Brien Benoit
Chair
Patented Medicine Prices Review (PMPRB)
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Box L40, Standard Life Centre
Ottawa, ON K1P 1C1

Dear Dr. Benoit:

The members of the Canadian Generic Pharmaceutical Association would like to express their appreciation to the Board for considering the recommendations of the CGPA/PMPRB Working Group in the latest round of Guidelines by setting apart generic patented medicines from brand medicines. Specifically, we are pleased that you appear to support the principles that a generic price that is below the brand price is not excessive and that international prices are not relevant to the price review of patented generic products. However, we are making a formal response to the draft Compendium regarding concerns we have, and hope that the Board will continue to fully engage with the generic industry in the process of adapting the Guidelines to truly recognize the unique characteristics and needs of the generic industry.

In the meantime, we would like to reiterate the proposals contained in the Working Group report regarding changes to the Regulations. The Working Group made a joint proposal that the Regulations be changed to move generic patented medicines to a complaints-based reporting system, much like the OTC and Vet drugs, and that generics be exempted from filing international prices, given their irrelevance in the price review. In face-to-face discussions with the Board, yourself and other members of the Board seemed extremely open to this possibility. However, the recent stakeholder Communiqué regarding patentees' reporting obligations made no mention of any plans to change the Regulations.

Generic medicines, like OTCs, face competition in both the distribution and consumer markets. It seems to be a unanimous conclusion that the low level of risk of excessive prices from generic products does not warrant a great deal of resource investment on the part of taxpayers or manufacturers. We strongly encourage the Board to promptly move forward with this process.

One additional issue that remained outstanding from the Working Group process was patentees' requirement for R&D filing found in the Regulations. Such a requirement was made as part of a "deal" between the government and the brand industry, to extend patent protection for brand medicines in return for maintaining R&D investment at a certain level in Canada. Generic companies were not privy to, nor did they benefit from, any such "deal".

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Any R&D investment by generic manufacturers is done willingly, and in fact, data will show that R&D spending by generic manufacturers surpasses that of brand manufacturers in Canada. It would be offensive to generic manufacturers for brand patentees to appropriate themselves of any R&D investment made by generic companies before Parliament. Combining R&D investment by generic and brand patentees in the reporting to Parliament as a whole would in fact artificially increase the R&D to sales ratio, and as a result be misleading to both the government and the public.

We would like to request a meeting with the Board to discuss these issues, and look forward to working towards achieving a satisfactory regulatory framework for price review of generic products in Canada.

Sincerely,

Jim Keon
President

CGPA Response to PMPRB Guidelines issued for Notice and Comment
Aug 20, 2008

The Canadian Generic Pharmaceutical Association (CGPA) is pleased to provide comments on the PMPRB's draft Compendium issued for Notice and Comment on August 20, 2008.

The following comments deal with the differences between the recommendations made by the CGPA/PMPRB Working Group with respect to generic Guidelines, and the proposed Guidelines for generic patented medicines found in the draft Compendium. Note that these suggestions are made on a without prejudice basis for purposes of cooperation with the PMPRB, and by no means are an admission that generic patented medicines fall under the PMPRB's jurisdiction.

Executive Summary

Since 2007, the CGPA has been engaged in consultations with the PMPRB with regards to new Guidelines for generic patented medicines. In May 2008, the CGPA/PMPRB Working Group made the following joint recommendations to the Board:

1) Generic medicines should be compared to the bioequivalent brand medicine at introduction.
2) International prices of generic medicines should never be applied to Canadian generic medicines.
3) Limiting ex-factory prices (the average transaction price) of generic medicines to inflationary increases would hinder competition in the pharmaceutical market. Moreover, generic list prices are already lower than brand prices by way of provincial regulation, and as such should not be restricted to CPI changes.
4) The *Patented Medicines Regulations* should be changed to allow for complaints-based reporting of generic patented medicines, and to exempt generic patentees from filing international prices.

The rationale for such changes to the Guidelines includes:

1) Generic patented medicines are unique from the brand patented medicines in that they operate in a competitive market.
2) Generic prices are already regulated by provincial governments to be lower than brand medicines.
3) Regulation of generic ex-factory prices does not translate into protection of consumer interests.
4) Regulating the prices of generic medicines in Canada cannot be achieved through the Patent Act since patented generics only make up a minority of generic medicines. Moreover, this would limit the ability of a patented generic manufacturer to compete against other manufacturers of the same medicine who do not have patents, since these will be free to change prices at will in reaction to the competitive environment.

CGPA Response to PMPRB Guidelines issued for Notice and Comment
Aug 20, 2008

Background

Throughout 2007, the generic industry met several times with the PMPRB to discuss the irrationality of subjecting patented generic medicines, which operate in a competitive, multi-source market, to the same rules as patented brand medicines, which hold market power and operate, for the most part, in a monopolistic market.

In January 2008, the PMPRB established a Working Group consisting of members of the Canadian Generic Pharmaceutical Association (CGPA) and the PMPRB Staff. The Working Group was given the mandate "to provide advice and options for changes to the Guidelines and Regulations that would consider the environment" in which generic patented medicines are sold.

The Working Group reported to the Board in May 2008 and made joint recommendations that recognize the inherent differences in the generic and brand industries and consider the realities faced by generic patentees in terms of market competition and provincial regulation.

Rationale for Different Generic Guidelines

Generic medicines are subject to market competition regardless of whether a "patent" is present. There is no known case where a patent held by a generic company resulted in a monopoly or which conveyed pricing power. This is unlike brand patented medicines, which rely on the temporary monopoly provided by the patent system and which conveys pricing power. The PMPRB was created in order to mitigate the risk of market power abuse in the more highly monopolistic market that would presumably arise as a result of increased patent protection for brand medicines. Generic medicines have not benefited from extended patent protection that stemmed from changes to the Patent Act. Therefore, subjecting generic patented medicines, which hold no market power, to rules that were written to prevent the abuse of market power, would prove an inequitable and irrational exercise of statutory authority granted by Parliament, not to mention a suboptimal utilization of public resources.

List prices of generic medicines are required under provincial legislation to be lower than brands. In this light, it would be unreasonable to consider generic prices, which are lower than non-excessive brand prices, to be excessive.

Regulation of ex-factory prices of patented generic medicines will have no impact on prices paid by consumers. Generic ex-factory prices do not reflect prices paid by consumers. Regulating ex-factory prices of generic medicines as per the Guidelines and Regulations does not translate into consumer protection.

The Board may recall that not every manufacturer of a given medicine has a patent pertaining to it. In fact, patented generic products comprise a minority of generic products and hold no pricing power over non-patented generics. While the companies with no patents will be free to engage in open competition, the patented generic product will be restrained from changing prices under the most recent formulation of the PMPRB Guidelines. This would be equivalent to choosing winners and losers in the pharmaceutical market.

Secondly, 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. Regulating the prices of generic medicines in Canada cannot be achieved through the Patent Act.

Generic Guidelines

Price Test for Introductory Review

It was the Working Group's view that generic medicines that are bioequivalent to the brand medicine should be compared only to the brand medicine. It is a rare occasion where a generic medicine would be launched once the brand is no longer sold. Exceptions such as these should be dealt with on a case-by-case basis. Generally, the price test for a generic medicine should be the price of the brand medicine.

Comparator Price Source

The draft Compendium mentions using an "appropriate public source". This vague reference is not acceptable. The previous Guidelines mention using ODB prices where available, and other formulary or non-formulary publicly-listed prices where such prices are not "appropriate". The brand price used should always be sourced from a published, public formulary.

The draft Compendium mentions using the highest previous published ATP of a comparator in TCCs for new medicines. The generic industry is of the view that whether or not this highest previous ATP is published, the same principle of using highest previous price should apply. Using highest previous <u>list</u> price from a public, published formulary is not inconsistent with the Board's principles, as was affirmed in the decision on Admissibility of Evidence for Adderall XR, where the Board Panel allowed the highest published formulary price to be used in the TCC for Adderall XR.

Alternatively, an average of the brand list price in the past 5 years before generic launch could be used in the generic price test.

International Price Comparison

The draft Compendium mentions waiving the "golden rule" of applying the international price comparison (IPC) to reference-based generic medicines only in cases where the brand product is sold in Canada. However, it will never make sense to apply the IPC to licensed or referenced generic medicines, whether or not the brand is being sold, for the following reasons:

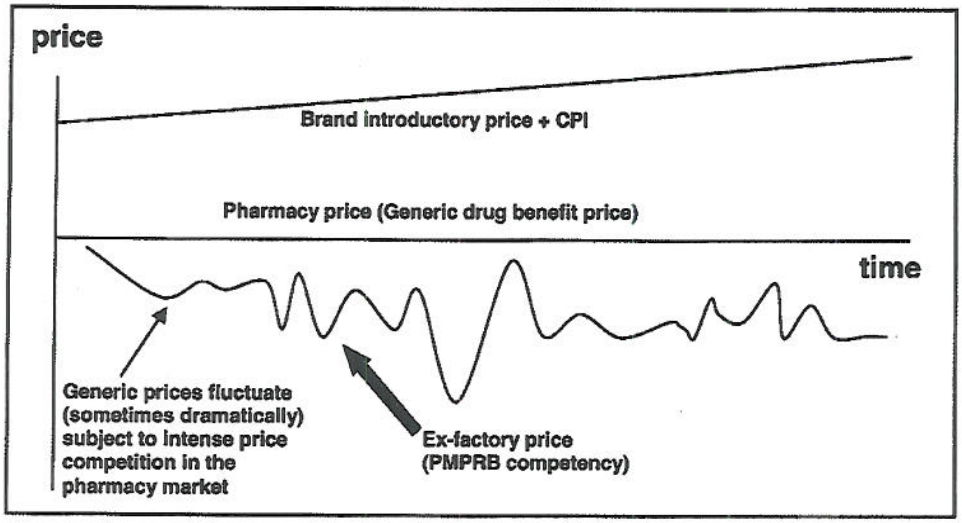
1) Competition and different price regulation in generic markets in other countries could contribute to significant volatility in international generic prices, which could indicate generic prices being "excessive" in one period but not in another based on the IPC test. Applying the IPC test to generic medicines could repeatedly trigger investigations unnecessarily and impose frequent fluctuations in Canadian generic prices, to the great disturbance of generic companies and customers alike.
2) Although international prices are indeed a factor to be considered in the Patent Act, the Board has the discretion as to the weight applied to each factor. This includes, presumably, giving preferential weight to one or another factor. That is not to say that the Board would not consider international prices for generic medicines, but merely that having considered international prices, these are viewed as less relevant than other factors.
3) Generic prices are perceived as being higher than in other countries. However, it is prices at the retail level that hold such a presumption and these "high" generic retail prices in Canada serve to contribute to the Canadian healthcare system by supporting community pharmacy.

Existing Price Test

It would be unreasonable to subject generic prices to the same price increase controls as patented brand medicines for the reasons listed below.

As already mentioned, generics compete at the ex-factory level, while retail prices are relatively stable. Ex-factory prices bear little relationship to retail (list) prices. Consumers are not affected by competition in ex-factory prices. Consequently, regulating ex-factory prices of generic medicines is unnecessary and unreasonable.

Price Competition in Generic Markets



In addition, list prices will always be the highest price charged to any customer in the country for any generic medicine. Yet, list prices are already regulated by provincial governments and as such will always be lower than brand prices. Moreover, price *increases* are amply controlled by provincial governments.

For this reason, the MNE for generic medicines should always be de-linked from the ATP. The generic ATP should always be presumed to <u>not</u> be excessive, rather than the opposite. Providing evidence every time a fluctuation greater than CPI occurred in the ATP would pose an onerous administrative burden on generic patentees, and would undoubtedly negatively impact the competitive edge of patented generic medicines.

Generic medicines are often sold at a different price to different customers. Due to the nature of the business and the various customers ranging from governments, provinces, hospitals, retail, and both private and public sectors at any one time, there may be a multitude of different prices for each customer. Invariably due to contracts won and lost there will always be units sold at the introductory generic price and there will be wide variances in the average price. Trying to determine the average selling price on any given day would be an exercise in frustration and would also prove to be a wasteful utilization of public resources, since generic prices will **<u>always</u>** be lower than brand prices.

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.

Transition Measures for Generic Patented Medicines

The PMPRB has not yet addressed any issues of transition with respect to generic and brand patented medicines to the new Guidelines. It is the opinion of the generic industry that any existing patented generic medicines should be grandfathered and presumed non-excessive. During talks with the Board members preceding the establishment of the CGPA/PMPRB Working Group, the Board members acknowledged the need for a different set of Guidelines applying to generic patented medicines. It follows then that the old rules were not appropriate for generic patented medicines. It would be unreasonable and a waste of public resources to continue any enforcement activities that subject generic medicines to the old rules. Likewise, there should be no back-filing of data. New generic Guidelines would apply to new patented generic medicines only.

Secondly, the PMPRB should move forward with changing the Regulations to move generic reporting to a complaints-based system, much like the OTC and Vet medicines. It is imperative, for the long-term health of the generic industry, that the realities in the generic market be recognized, and that no administrative or regulatory burden be imposed that would be disproportionate to the benefit gained for consumers and the healthcare system.