Report of CGPA/PMPRB Working Group on
Options for Changes to the PMPRB's
Excessive Price Guidelines to Reflect the Unique Nature
Of Patented Generic Medicines Sold in Canada

I Introduction

The Working Group has held four meetings to-date to carry out the duties outlined in its Terms of Reference (see Appendix 1). [1]

An over-riding rationale for the proposal for tailored Guidelines for generic medicines is that the generic market is characterized by significantly different competitive forces from the brand pharmaceutical environment, and most competitors are non-patented. It is essential that the Board's role in determining whether prices of patented medicines are excessive not inadvertently impede the need and opportunity for patented generics medicines to compete with other non-patented medicines.

The generics market is further impacted by public drug plan legislation and policies which designate generic medicines as interchangeable for dispensing purposes, and set rules for pricing relative to reference brand medicines. The market's view that generics are interchangeable means that these products must compete on terms that are not tied to product differentiation. In fact, the predominant area for competitiveness is through rebates and professional allowances to wholesalers/pharmacies to obtain preferred dispensing. This is also unlike the brand pharmaceutical environment where competition is highly related to the innovative advantages of patented medicines for patients.

Similar to the generic market in Canada, generics in the PMPRB's comparator countries are highly competitive and prices may be differentially impacted by the different nature of the generic industry in those markets (e.g. more and different generic companies than exist in Canada) and national price negotiation policies and practices. For this reason, the Working Group believes that a determination of excessive pricing for patented generics in Canada must be tied to domestic price tests, and international prices, while reviewed, should generally not be used to set a maximum non-excessive price for the Canadian market.

As a context for its work, the Working Group has identified three types of patented generic medicines:

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[1] These proposals do not limit the rights of individual generic companies.

1) A patented generic medicine where a licence to sell the product has been issued to a generic patentee by the patent holder. In this case, for purposes of granting a Notice of Compliance, the generic patented medicine is cross-licensed with the brand medicine. In fact, the generic medicine is identical to the brand medicine (same chemical, dosage form, strength and patent) but is being sold by the patent holder and, as authorized generic, by a generic company.

2) A patented generic medicine that has the same chemical, dosage form and strength as a reference brand medicine, but also has a processing/manufacturing patent unique to the generic drug product. The granting of a Notice of Compliance is based on an Abbreviated New Drug Submission (ANDS) where the clinical trials of the reference brand are cross-referenced. These generic drug products are also determined by Health Canada to be bioequivalent to the brand drug as the processing/manufacturing patent may add efficiency to the medicine's production but does not change the ultimate bioavailability and action of the ingredient medicine.

3) A patented medicine that has the same chemical, dosage form and strength as a reference brand medicine but has a unique delivery patent that changes the ultimate nature of the drug such that it is not considered bioequivalent to a brand product. In these cases, a Notice of Compliance is granted pursuant to a New Drug Submission.

The Working Group proposes that the following tailored Generic Guidelines only apply to the first and second type of patented generic drug product as these are, for all intents and purposes, the "same" medicine as the cross-licensed or cross-referenced brand drug product. However, the third category would be subject to the normal Guidelines applied to patented brand drug products.

II Proposed Tailored Generic Guidelines

Scientific Review Procedures

<u>Selection of Comparable Medicines</u>

Category 1 and 2 (see above) patented generic medicines will not be reviewed by the Human Drug Advisory Panel for degree of therapeutic improvement, since they are essentially the "same" medicine as the brand medicine. The only and automatic comparator drug product will be the cross-licensed or cross-referenced brand medicine.

Procedure

The Generic Patentee will make a submission at the time of the filing of Form1, Identity of the Medicine to the effect that the new drug qualifies as a cross-licensed or cross-referenced generic.

Price Tests

Introductory Price Tests for Patented Generics

Therapeutic Class Comparison Test

Category 1 and 2 patented generic drug prices will be considered non-excessive if they do not exceed the price of the cross-licensed or cross-referenced brand product cited in the ANDS.

International Price Comparison (IPC) Test

For a cross-licensed or cross-referenced patented generic drug product, an IPC test will be conducted. In the case of a cross-licensed patented generic drug product, the prices of the same medicine internationally will include the prices of the cross-licensed brand and, if available to the generic patentee to report, the prices of other licensed generic drug products in the comparator countries.

Given that the non-excessive Canadian brand medicine price cannot be the highest in the world, it will always be true that the price of the cross-licensed Canadian generic medicine will be lower than the Highest Price in the International Price Comparison by virtue of higher prices for the brand drug.

It is proposed that the PMPRB undertake to amend its Patented Medicines Regulations to remove the requirement to file international prices (Block 5, Form 2) for cross-licensed and cross-referenced generics.

Procedure

The Generic patentee will attempt to obtain information on international prices of the cross-licensed brand drug and on any other licensed generic products in the comparator countries for purposes of filing requirements under the Regulations. However, it is recognized that information on the existence and prices of other licensed generics may not be made available to the generic Canadian patentee by the patent holder due to restrictions within licensing agreements that the terms confidential to the parties to each license.

For a cross-referenced patented generic medicine, the “same medicine” in the comparator countries will be limited to the Canadian generic company’s medicines sold internationally (if at all). The cross-referenced brand is not

considered the "same medicine" for the purposes of filing requirements to the PMPRB as it does not share the same patent as the generic medicine.

Given the different nature of generic markets in the comparator countries it is possible that the price of the Canadian patented generic medicine will fail the Highest International Price Comparison test – i.e. the Canadian price could be higher than the prices in the comparator countries. If this occurs, it is recommended that this not result in determination that the price of the Canadian patented generic medicine is excessive, on the basis that, for the unique generic market reasons discussed above, the primary test for the generic medicine should be the domestic TCC test. Otherwise, if the price of the Canadian patented generic medicine was forced down to the Highest International Price, this would likely mean, due to the price rules of provinces/territories for generics, that a patented generic medicine's maximum non-excessive price would be reduced below the highest price of its domestic non-patented generic drug competitors.

International Therapeutic Class Comparison Test

For a cross-licensed and cross-referenced generic medicine, the comparators included in the International Therapeutic Class Comparison Test would include all brand and generic medicines sold internationally that have the same chemical ingredient, dosage form and strength. Given the significant differences in the number of generic companies and generic medicines internationally, and the highly variable international markets in which they compete, the results of this test would not be useful.

Price Tests for Existing Patented Generic Drug Products – Delinking Methodology

For a new patented generic drug product, the introductory MNE price will be the price of the cross-licensed or cross-referenced brand, and this will remain the price in future periods unless and until the price of the patented generic drug product exceeds this introductory MNE price.

Generic drugs use, as their main form of price competition, rebates and professional allowances to wholesalers/pharmacies, which are not passed on to a paying customer (patient or third party insurer). In the event that the Average Transaction Price (ATP) declines from the previous year, due to the increase or decrease in rebates, professional allowances or other like benefits, the calculation of the MNE price for the following year would be based on the higher of the introductory MNE price or, if the introductory MNE price had been exceeded and the MNE price was being determined by the Board's usual CPI Methodology, the highest previous non-excessive ATP.

In terms of a one-year price increase, the generic patentee would have the option to separately file with the Board Staff information on changes in rebates, professional allowances or other like benefits which have caused the price fluctuations leading to a price appearing to be excessive. If the Board Staff determines that the apparent excessive price increase is solely due to a change in rebates, professional allowances or other like benefits, no one year price cap would be applied as the changes would solely reflect competition at the wholesaler/pharmacy level that are not passed on to a patient or third party payer.

In the case where there has been some real change in the price of the patented generic medicine, and a price increase cap is applied to moderate the "rebound" to the MNE price, the Working Group has yet to recommend how this price increase cap would be determined and will await the views of the Working Group on Price Tests prior to further considering a possible tailoring of the cap to the generic market.

It is proposed that the PMPRB move to amend the Regulations to remove the requirement for generic patentees to include rebates, professional allowances and other like benefits in the ATP calculation.

Regulatory Amendments

In addition to the proposed amendments to the reporting requirements noted above (i.e. remove the need to report international prices of the medicine and to include rebates in the ATP), it is recommended that the Board consider a regulatory amendment that would move cross-licensed and cross-referenced (bioequivalent) patented generic drug products to the same complaints-based reporting enacted in the recent Regulatory amendments for vet and OTC drugs.

Appendix 1

TERMS OF REFERENCE
CGPA/PMPRB WORKING GROUP ON GUIDELINES PERTAINING TO THE PRICING OF PATENTED GENERIC DRUG PRODUCTS

Revised February 7, 2008

MANDATE

The mandate of the Working Group (WG) is to provide advice and options for changes to the Guidelines and Regulations that would recognize the environment in which generics are sold for consideration by the Board.

DELIVERABLES

1. Advice and options for changes to the Guidelines and Regulations pertaining to the review of patented generic drug products.
2. Background information supporting the advice and options.

REPORTS &TIMEFRAME

Status/progress report to Board by March 5, 2008

Report to the Board by the end of April 2008 Presentation to the Board on advice and options in May 2008

MEMBERSHIP

The Working Group (WG) shall be composed of members from the PMPRB and CGPA including:

Senior PMPRB staff members including the Executive Director.

Members appointed from the generic pharmaceutical companies as well as the President of the Canadian Generic Pharmaceutical Association.

Records of decisions and action steps will be prepared for meetings of the Working Group and circulated to all participants.

Additional Views of the CGPA

Principles

Generic medicines are medicines for which approval by the Minister of Health was sought and granted on the basis that the medicine is the pharmaceutical equivalent of another medicine, or on the basis of a cross-reference to another medicine either through Health Canada marketing approval or through provincial regulation.

The generic companies were never meant to benefit from, and were actually harmed by, the amendments to the *Patent Act* stemming from Bills C-22 and C-91. The CGPA believes it is against the very principle of streamlining regulation and the spirit of the PMPRB's mandate to now apply the same restrictive Guidelines and Regulations on generic medicines that happen to hold patents, which for the most part do not provide the patent protection as intended by those amendments.

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

Furthermore, the Board's ability to regulate the patented generics does not have a direct impact on the price paid by consumers. Generic ex-factory prices often bear little or no resemblance to prices charged to consumers and any savings offered to pharmacies through fierce ex-factory price competition are rarely passed on to consumers[1]. Regulating ex-factory prices as per the *Regulations* would have limited impact on prices paid by consumers.

Generic retail prices are generally determined by provincial governments, either directly or indirectly. Ontario's Bill 102 and Quebec's Bill 130 have evidenced this by requiring multi-source generic list prices to be 50% of brand prices. As a result of recent provincial policy changes, generic companies have taken major price reductions, which have contributed to significant cost savings to provincial drug plans in those provinces. Brand companies, on the other hand, have largely offset these cost savings by taking price increases.

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.

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.

Support for Proposed Measures

Power to exercise authority
The Board has wide latitude in exercising its mandate. The Board exercised its discretionary powers in 1993 by deciding to assign greatest weight to the CPI factor in the review of existing medicines in the patented brand industry[2]. Also, more recently in the Leo case, the courts have ruled that the Board has the right to assign different weights to the factors included in Section 85(1) of the *Patent Act*. This was confirmed in the Copaxone and Adderall XR decisions. This means the Board may assign a weight of zero where in its judgement, it is appropriate to do so. The most important factor for generic medicines is the price of the brand medicine, which is included in factor (a), the prices of the medicine in the relevant market.

In addition, the Board has exercised its authority to differentiate what data should be filed for products in different marketing regulatory schedules. Veterinary and OTC drugs are examples which have been enshrined in the Regulations. Previously the Board adopted the complaint-based policy for veterinary drugs via policy and achieved the desired objectives.

Copaxone Decision
The Board acknowledged the need to consider other factors than only CPI in the case where the price of a medicine was lower than its comparators. Moreover, the Board pointed out the absurdity of considering such a price excessive, regardless of the level of increase taken.

> "The Board confirms its comments made above whereby it allocates the greatest weight to the CPI factor in paragraph 85(1)(d) in situations concerning increases in prices of existing medicines. The Board agrees however, that fact situations involving price increases similar to the circumstances of Copaxone in this matter cross a threshold where the CPI factor <u>should not be the sole determinant</u> of whether a price increase is excessive. In other words, the Board is prepared to recognize that the factors in paragraphs 85(1)(b) and (c) should apply to situations involving

[2] Bulletin 9, October 1992.

> an increase in the price of a medicine that was and remains the lowest in a group of medicines of its therapeutic class... (emphasis added)
>
> The Panel is prepared to adopt this interpretation of the Act because it is of the view that at some point the price of a medicine relative to that of the other medicines in its class, which are the measures referred to in paragraphs 85(1)(b) and (c), can be so low that it flies in the face of common sense to conclude that the medicine is excessively priced merely because the increase exceeds the CPI." [paragraphs 45-46; emphasis added]

Where a generic is priced below the level of the brand, this same logic would suggest that the price cannot be considered excessive solely on the basis of a price increase exceeding CPI.

Discussion Paper

In the Discussion Paper released by the PMPRB in January, the Board made proposals concerning a new CPI adjustment methodology that would make the introductory MNE a *floor price* rather than a moving *maximum* price. These proposals demonstrate that setting the brand price as the generic medicine's MNE, is not only consistent with the *Patent Act* and the *Regulations*, but also supports the mandate of the PMPRB to ensure prices are not excessive.

"It can be argued that if a previous average price was not excessive under the Board's Guidelines, then intuitively a price below this previous average price should also not be excessive simply as a result of the CPI-adjustment methodology… [The] introductory MNE price, as established by the appropriate price test(s), would have been acceptable to the PMPRB if the medicine had actually been sold at this price at introduction." (Discussion paper, p.16-17).

Cost of Regulating Patented Generics

PMPRB regulation needs to be cognizant of the fact that Canadian generic companies were not meant to nor did they benefit from the amendments to the *Patent Act* stemming from Bill C-22 and Bill C-91. Applying the same regulation on patented generic medicines requires a great deal of resources, both on the part of the patentees and Board Staff and will achieve very little in the form of protection from excessive prices, when generic prices are, by definition, lower than the pre-entry brand prices.

Any regulatory burden imposed on patented generic manufacturers must be proportionate to the resulting benefit for society and consumers.

The Federal Government recently gave direction with respect to regulation of competitive industries by stating that regulation should yield to competitive forces to achieve policy objectives to the extent possible, and measures used in

regulation need to be "efficient and proportionate to their purpose and [should] interfere with the operation of competitive market forces to the minimum extent necessary"[3].

The Federal Government also recently issued direction regarding costs of regulation in its *Cabinet Directive on Streamlining Regulation*[4], which became effective on April 1, 2007. The directive reads:

> "When regulating, the federal government will … advance the efficiency and effectiveness of regulation by ascertaining that the benefits of regulation justify the costs, by focusing human and financial resources where they can do the most good, and by demonstrating tangible results for Canadians;" (emphasis added)

In selecting appropriate government instruments to achieve policy objectives,

> "• departments and agencies are to demonstrate that the regulatory response is proportional to the degree and type of risk;
>
> "• demonstrate that the regulatory response will not unduly affect areas that it was not designed to address;" (emphasis added)

Finally, when determining how to engage in regulation, departments and agencies should assess the costs and benefits of measures and develop options that maximize net benefits. These options should:

> "• limit the cumulative administrative burden and impose the least possible cost on Canadians and business that is necessary to achieve the intended policy objectives;
>
> • consider the specific needs of small business and identify the least burdensome but most effective approach to addressing these needs;
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> • ensure that regulatory restriction on competition is fair, limited, and proportionate to what is necessary to achieve the intended policy objectives;" (emphasis added)

Imposing the current Guidelines and reporting requirements found in the *Regulations* would be inconsistent with the Federal Government's objective of

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[3] Order Under Section 8 of the Telecommunications Act – Policy Direction to the Canadian Radio-Television and Telecommunications Commission, available at http://canadagazette.gc.ca/partI/2006/20060617/html/regle5-e.html.

[4] Cabinet Directive on Streamlining Regulation, available at http://www.regulation.gc.ca/directive/directive-eng.pdf.

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 of protecting the interests of consumers, not to mention inflict substantial administrative burden on both Board Staff and patentees.