Canadian Generic Pharmaceutical Association Submission

PMPRB Guideline Modernization Consultations

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INTRODUCTION

The Canadian Generic Pharmaceutical Association (CGPA) is the national association representing Canada's generic pharmaceutical industry, a group of companies which specialize in the production and marketing of high quality, affordable generic drugs.

For more than 50 years, Canada's generic pharmaceutical industry has played a vital role in the country's health-care system and its economy by providing safe, effective, proven alternatives to more expensive brand-name medicines.

Increasing patient access and helping to ensure the affordability and sustainability of drug benefit plans and the broader health-care system is a core value of Canada's generic pharmaceutical industry.

In Canada, generic medicines are dispensed to fill fully 69 per cent of all prescriptions but account for account for only 22 per cent of the $25-billion Canadians spend annually on prescription medicines. The CompassRx Report released by the Patented Medicine Prices Review Board (PMPRB) in March 2015 confirms that the most significant factor for controlling prescription drug costs in Canada is increased use of generic prescription medicines.

The CGPA is pleased to provide this submission in respect of the PMPRB's Guidelines Discussion Paper of June 2016.

The PMPRB Framework[1] was not established in a manner that took into consideration the particular market dynamics unique to generic drug products, let alone Patented Generic Drugs.[2] Generic drug prices are regulated in a sophisticated manner by individual provinces and territories, and more recently by the federal, provincial, and territorial governments collectively through the pan-Canadian Pharmaceutical Alliance ("pCPA").

In order to accommodate for the market dynamics unique to generic drug products, the PMPRB Framework should be amended to specify that:

- brand and generic drugs are separate categories of product, in order to allow for differential treatment of those product categories under the PMPRB Framework;
- investigations into Patented Generic Drugs will be initiated by the PMPRB only where all of the following criteria are met:
    - a complaint is received by the PMPRB regarding the pricing of the Patented Generic Drug;

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[1] The "PMPRB Framework" refers to the applicable provisions of the *Patent Act* and *Patented Medicines Regulations* in relation to the PMPRB, the case law interpreting those provisions, as well as the various guidelines and policies issued by the PMPRB to date. In proposing amendments to the PMPRB Framework, the CGPA recognizes that the case law cannot be amended.

[2] As discussed in greater detail below, Patented Generic Drugs are a subset of generic drugs that fall within the scope of the claims of a patent owned or licensed by a generic manufacturer.

    - the Patented Generic Drug is the only one available on the market (i.e. no other equivalent generic or brand drug is available);
    - the price of the Patented Generic Drug is higher than the highest (historical) brand price, adjusted for CPI increases over the years as permitted by formulary rules; and
    - the Patented Generic Drug is non-compliant with pCPA or provincial formulary pricing, including any price increases permitted within those regimes.
- customer and wholesaler discounts and/or rebates, across a basket of products, should be expressly accounted for when making determinations under the excessive pricing analysis; and
- there will be no retroactivity in respect of the PMPRB Framework in respect of Patented Generic Drugs.

Application of Current PMPRB Framework to Generic Drugs

The PMPRB regime was created to limit the prices set by patentees of brand drugs sold in Canada to ensure that those prices were not excessive. For the reasons set out below, applying the PMPRB Framework to generic drugs, and not distinguishing between brand and generic drugs, is not in the public interest for a variety of reasons.

Generic drugs are commodity products with slim profit margins. In contrast, brand drug products are sold with profit margins that are several multiples of the cost of production of the drug product. Prices for brand drugs tend to be related to the perceived medical value of the product viewed in the context of a product monopoly based on the assertion of patent rights.

Given the slim profit margins of generic drug products, generic drug prices are highly sensitive to input and manufacturing costs (e.g. price increases for the active pharmaceutical ingredient, excipients, and direct and indirect manufacturing costs). As a result, as an example, foreign exchange rates (i.e. changes in the value of the Canadian dollar) can wreak havoc on global supply chains and the input and manufacturing costs of generic drug products.

These increases in the cost of ingredients or manufacturing can often be dramatic over a short time period (e.g. a shortage of the active pharmaceutical ingredient due to a small market for the product in question, or a rapid fall in the value of the Canadian dollar). Most significantly, these cost increases can quickly turn a generic drug product with a slim profit margin to one with slim or even substantial losses.

On occasion, some generic manufacturers may be prepared to continue selling such a product at a loss, at least for a time, since patients rely on the supply of the product and there can be commercial advantages to having a larger product portfolio, notwithstanding a money-losing product. Moreover, the cause of the underlying cost increase may return to previous levels after a time. On the other hand, the commercial reality is that a manufacturer cannot sell an unprofitable product indefinitely, and an

increase well beyond the Consumer Price Index may well be required in order for the product to remain commercially viable.

As described in greater detail below, application of the PMPRB regime to generic drug prices could have severe, unintended consequences that would be contrary to the public interest, including:

- market withdrawal of the generic drug(s) if the necessary price increase exposes the manufacturer(s) to significant liability; this in turn leads to fewer versions of the generic drug product on the market, and a greater likelihood of drug shortages of the product;
- market withdrawal of a generic version of a multisource product if the manufacturer has a patent that requires reporting of the product to the PMPRB, and competing generic manufacturers of the same interchangeable product do not have such purported patent rights, thereby putting the first manufacturer at a severe competitive disadvantage (e.g. due to increased costs from PMPRB reporting and risk of liability) resulting in market withdrawal of that generic drug product and potential price increases for the generic drug products that remain on the market;
- the imposition of additional, and significant, regulatory costs on generic manufacturers in respect of the PMPRB Framework which would be more appropriately allocated to generic drug development, lower prices, and patient support programs, for example.

Application of the PMPRB Framework to generic drugs is also at odds with provincial regulation of generic drug pricing, and will have detrimental effects on provincial and territorial efforts directed to minimizing drug shortages and ensuring drug supply.

Current Pricing Regime for Generic Drug Prices in Canada

Pricing of generic drug products is regulated by the provinces and territories, both individually and collectively, in a sophisticated and effective manner.

Provincial Formulary Pricing

While the approach varies across the provinces and territories, provincial formulary pricing mechanisms include:

- fixed-percentage pricing (i.e. the generic drug is set at a small fraction of the equivalent brand drug, such as 18% of the equivalent brand drug product); and
- Price referencing (e.g. the price of the generic drug is set in reference to the lowest price for the drug available in other provinces).

Historically, provinces had taken a “one price fits all” approach to drug pricing. Moreover, as governments sought to cut costs and control budgets, provincial formularies set ever lower prices for all generic drug products using the "one price fits all" approach.

pan-Canadian Pharmaceutical Alliance ("pCPA")

The federal, provincial, and territorial governments have also pooled their resources and approach to generic drug pricing. In this regard, in July 2012, Premiers in the Council of the Federation announced a Generic Value Price Initiative to achieve better prices for generic drugs and improve consistency in pricing and approach.

On January 18, 2013, a joint approach was announced in respect of achieving the lowest generic drug prices to date in Canada. Effective April 1, 2013, the first phase established a price point for six of the most commonly dispensed generic drug products at 18% of the equivalent brand drug product: atorvastatin, ramipril, venlafaxine, amlodipine, omeprazole, and rabeprazole. In each subsequent year, additional generic drug products have been added. In April, 2014 four additional products were priced at 18% of the equivalent brand drug product: rosuvastatin, pantoprazole, citalopram, and simvastatin. In April 2015 another four generic drug products were added: clopidogrel, gabapentin, metformin and olanzapine. Most recently, in April 2016, four more generic drug products were added to the list: donepezil HC, ezetimibe, quetiapine, zopiclone. As such, there are currently 18 products priced in Canada at 18% of the corresponding brand drug product.[3]

The Pan-Canadian Generic Value Price Initiative Generic Pricing Framework was implemented effective April 1, 2014. It employs tiered pricing based on the number of generic versions, of the corresponding brand drug, on the market.[4] In a competitive market, where there are three or more generic products (i.e. "multi-source") that are equivalent to the corresponding brand drug product, the price is set for those products at a maximum of 25% of the brand drug product for solid dosage forms (e.g. tablets and capsules), and a maximum of 35% of the price of the brand drug product for dosage forms other than oral solids (e.g. liquids, patches, injectables, inhalers, etc.), as those products are typically more expensive to manufacture.

For generic products where there are only two generic drug products that are equivalent to the brand drug product (i.e. "dual source"), the pCPA sets the price at a maximum of 50% of the brand drug product. Where there is only one generic drug product in the market corresponding to the brand drug product (i.e. "single source" generic), then the price is set at either a maximum of 75% or 85% of the brand drug product, depending on whether the manufacturer of the brand drug product pays a discount to a province in respect of the supply of that brand drug product.

The foregoing pricing regime has been adopted by the federal, provincial, and territorial governments for reimbursement, given that those governments themselves established the pCPA. As a result, the federal, provincial, and territorial governments have been amending and adapting their government-funded drug programs accordingly.

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[3] See: www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pricing-alliance

[4] See: http://formulary.drugplan.health.gov.sk.ca/PanCanadian.aspx

Instances requiring price increases for generic drug products tend to arise with products that have been on the market long past the expiry of the brand product monopoly. At some time subsequent to the expiry of the brand product's market monopoly, the drug product enters the "decline" part of the drug life cycle, and the drug product's utilization falls. At this point, production costs rise due to declining economies of scale and higher direct and indirect production costs. As a result, some manufacturers leave the market at this stage potentially resulting in drug shortages for that drug product if the remaining manufacturers encounter supply chain challenges as they attempt to meet demand at existing prices. Federal, provincial, and territorial governments, both individually and collectively through the pCPA, have recognized that there are circumstances where price increases, well beyond the Consumer Price Index, are in the public interest in order to maintain continued supply of certain generic drug products.

The pCPA tiered pricing framework is a recognition that there is a relationship between generic drug pricing and the stability of supply of generic drug products. The continued commercial viability of certain generic drug products is sensitive to the various factors set out in this submission.

It is clear that the landscape for generic drug pricing is in sharp contrast with that of the pricing for brand drug products. The pricing for brand drug products is based largely on a negotiation between brand manufacturers and the provinces where there can be uneven bargaining power and assertion of patent monopoly rights. Generic drugs pose no such risk. The upper price of a brand drug product is limited by the PMPRB's price regulation. In addition, the province's determination of an appropriate price for the brand drug product is determined by the market monopoly for the product as well as the perceived medical value of that drug product relative to comparative drug therapies.

Canada is recognized as a market with high costs and barriers to entry for generic medicines, In recognition of this, the current pCPA pricing framework provides Canadians with generic drug prices that are internationally-competitive and sustainable.

The PMPRB was established to ensure the prices set by patentees of drugs sold in Canada were not excessive. CGPA notes that “affordability” is addressed in multiple sections of the PMPRB Guidelines Modernization Discussion Paper. The exercise of evaluating if the price of a drug is “affordable” is different from the one of evaluating if such price is “non-excessive”. The latter implies an abuse of the monopoly granted to the patentee – which was the stated intent of Parliament – while the first is mostly related to the ability to pay of a payer, either private or public.

CGPA is concerned that such a shift may go beyond the scope of the PMPRB’s legislated mandate. We are also concerned that such a dramatic shift in the PMPRB’s approach to brand-name drugs could have unintended negative consequences for the sustainability of generic drug prices in Canada, which are already affordable for Canadians as 5 to 6 generic prescriptions can be filled for the price of one brand-name prescription.

PROPOSED AMENDMENTS TO PMPRB FRAMEWORK FOR GENERIC DRUGS

In our view, it is essential that the PMPRB Guidelines draw a distinction between brand and generic drugs, so that it can be made clear that the PMPRB regime does not apply to the latter.

The PMPRB Framework Should Distinguish Patented Brand Drugs from Patented Generic Drugs to Enable Differential Treatment

Generic Drugs

Generic drugs are subsequent entry drug products, meaning that they enter the market after the brand drug has been introduced to the market typically via an abbreviated new drug submission (ANDS) to Health Canada.

Health Canada describes a generic drug product as a copy of the brand name product, and Health Canada refers to brand name products as the "Canadian reference product". Provincial governments, in establishing their drug reimbursement formularies, often use the term "original product" to describe the brand drug product.

Patented Generic Drugs

Some subset of generic drugs might fall within the scope of the claims of a patent owned or licensed by a generic manufacturer (a "Patented Generic Drug", as discussed above). Nevertheless, such Patented Generic Drug products would not benefit from their patent(s) due to reference pricing.

Put another way, the manufacturer of a Patented Generic Drug does not have any so-called "market power" in relation to the Patented Generic Drug. To the extent that the manufacturer of a Patented Generic Drug raises the price for that product, it will lose market share to other manufacturers of the same generic drug sold by other manufacturers. In the event that the Patented Generic Drug is sole source generic, then a price increase will simply attract market participation by other manufacturers causing them to introduce their own version of the generic drug, and driving down the price of the product as per the pCPA framework. Putting it bluntly, any patent rights attributed to a Patented Generic Drug do not result in any exercise of monopoly pricing power for that product.

Proposed Amendment to the PMPRB Framework

Generic drugs should be defined under the PMPRB Framework as encompassing:

- drugs that have been approved by Health Canada as equivalent to a Canadian reference product on the basis of a comparison to a Canadian reference product (e.g. as per C.08.001.1, C.08.002.1, and C.08.004(4) of the *Food and Drug*

Regulations for prescription drugs);
- drugs that are approved by Health Canada as a licensed version of an existing Brand reference product sold in Canada (e.g. a X-REF submission); or
- drugs that have been declared interchangeable to an original drug by a provincial/territorial/federal reimbursement formulary.

The PMPRB Framework Should Set out the Investigation Process for Patented Generic Drugs

The PMPRB Framework should provide clarity to generic manufacturers in respect of under what circumstances investigations into the pricing of Patented Generic Drugs will be initiated.

Proposed Amendment to the PMPRB Framework
Investigations into Patented Generic Drugs will be initiated by the PMPRB where all of the following criteria are met:

- a complaint is received by the PMPRB regarding the pricing of the Patented Generic Drug;
- the Patented Generic Drug is the only one available on the market (i.e. no other generic or brand drug available);
- the price is higher than the highest (historical) brand price, adjusted for CPI increases over the years as permitted by formulary rules; and
- the Patented Generic Drug is non-compliant with pCPA or provincial formulary pricing, including any price increases permitted within those regimes.

The PMPRB Framework Should Clarify that Patent Licenses will not be Implied

In past matters involving generic drugs, the PMPRB has implied patent licenses in a wide variety of circumstances in order to assert jurisdiction and seek penalties for excessive pricing.

A “we know it when we see it” approach by the PMPRB, in respect of when a generic drug is a Patented Generic Drug, does not provide clarity or predictability to generic manufacturers. Instead, this approach:

- thwarts compliance with the PMPRB Framework due to regulatory uncertainties and ambiguities;
- dramatically increases costs associated with efforts by manufacturers aimed at compliance;
- results in some generic drug products not being brought to market, or products being withdrawn from the market, due to uncertain compliance and exposure to potential liability under the PMPRB Framework; and

- prevents prospective risk minimization exposing manufacturers to financially crippling, and unpredictable, liability several years after the fact.

As a result, the PMPRB Framework must provide clarity as to under what, if any, circumstances a generic drug would be interpreted as being a Patented Generic Drug.

Of significant concern is under what circumstances, if any, a patent license might be implied to a generic manufacturer, in respect of a generic drug, under the PMPRB Framework.

This concern arises under two broad scenarios, as described in greater detail below: (1) patent licenses implied between a manufacturer and the manufacturer's raw ingredient suppliers; and (2) implied licenses to the patents of the brand manufacturer.

The simple approach to resolving these concerns is for the PMPRB Framework to apply the Supreme Court of Canada decision of *Eli Lilly & Co. v. Novopharm Ltd*., [1998] 2 S.C.R. 129 ("*Eli Lilly*"). In *Eli Lilly*, the Supreme Court of Canada considered the legal effect of supply agreements in respect of patent rights, and whether a sublicense was granted in the context of a supply agreement. In particular, the Court considered the distinction between a patent license and an ordinary agreement of purchase and sale. The Court noted that a sub-licensee can obtain the rights to use and sell a patented article if those rights are transferred by license; similarly, the sale by a licensee of a patented article is presumed to give the purchaser the right to use or sell or deal with the goods as the purchaser pleases. However, the sale of a licensed article obviously does not have the automatic effect of constituting the purchaser a licensee themselves, even though the purchaser enjoys rights of use and alienation. As set out by the Court, rights of use and alienation can only be determinative of the existence of the granting of a license in instances in which it is clear that no transfer of property rights has occurred (i.e. there has been no sale of the patented article to the third party, but the third party nevertheless has rights to make and well the patented article).[5]

In short, **the mere purchase and sale of drug ingredients from a supplier should not be construed as a patent license in the context of the manufacture of generic drugs, subject to express patent license rights otherwise conferred**.

Drug Ingredient Suppliers

Many ingredients and components of any given drug product are out-sourced to third parties by drug manufacturers, including generic drug manufacturers. As a result, a generic manufacturer, for any given product, may rely on multiple third party suppliers in respect of supplying the active pharmaceutical ingredient, and numerous non-medicinal ingredients contained in the drug formulation, such as tablet coatings, for example.

Any of these ingredient, or component, suppliers could have a multitude of patents that pertain to a medicine. Those patents are either irrelevant to the drug ingredient being

[5] *Eli Lilly & Co. v. Novopharm Ltd*., [1998] 2 S.C.R. 129 at paras. 68-79.

sold, or to the extent relevant, no patent rights, let alone exclusive patent rights are being conferred from the ingredient supplier to the generic manufacturer.

Generic drug manufacturers often rely on numerous third party ingredient suppliers in global supply chains. It would be an unreasonable obligation to impose on generic manufacturers to require them to audit the patent rights of their suppliers particularly when no patent rights are intended on being licensed by the generic manufacturer, and the transaction is merely an ordinary agreement of purchase and sale.

The industry requires **clarity that patents rights of third party drug ingredient suppliers supplying generic manufacturers will not be construed as a implied patent license when the transaction is a mere purchase and sale of drug ingredients from a third party supplier**.

Navigating the Third Party Patent Landscape

Generic drug manufacturers, in bringing a generic drug to market, must navigate the patent landscape. There are two reasons for this: (1) to determine whether the company will infringe a third party patent, and thereby incur potential liability for patent infringement; and (2) to comply with the requirements of the *Patented Medicines (Notice of Compliance) Regulations*, ("*PM(NOC) Regulations*") if applicable, before its marketing authorization can be granted.

Subject to regulatory approval by Health Canada, routes to market entry for generic drug products, in relation to patents, include the following:

- awaiting the expiry of any relevant patents, whether those patents are owned by the brand manufacturer or third parties;

- dismissal of an application brought by the brand company under the *PM(NOC) Regulations*; or

- settlement of an application brought by the brand manufacturer under the *PM(NOC) Regulations* or other patent litigation (e.g. on the basis of non-infringement; by agreement to postpone launch of the generic drug until the brand manufacturer's market exclusivity is otherwise lost; or on the basis that generic launch will follow on a specific day, but that liability for patent infringement will be waived by the brand manufacturer).

There are often numerous patents that might be asserted, by third party patentees, to be infringed by a particular generic drug product. The absence of patent litigation between the patentee and the generic manufacturer does not imply that there is a patent license between those parties.

Instead, there are a variety of reasons why a patentee might never assert a particular patent against a generic manufacturer's generic drug product. For example, the patentee may know or believe: (i) that the generic drug does not infringe the patent; (ii) that the patent is invalid and therefore not worthy of patent litigation (e.g. the

corresponding patent was invalidated in another jurisdiction); or (iii) that the patentee's entitlement to damages for infringement would be non-existent (e.g. no entitlement to damages due to the existence of non-infringing alternatives).

In short, there are several explanations as to why a third party patentee may not assert their patent rights against a generic drug product. Implying a patent license does not reflect the commercial reality. This is particularly the case since the generic manufacturer has likely performed an extensive analysis of whether the patent is infringed, invalid, and if infringed/valid, what the liability for infringement might be. In view of that analysis, the generic manufacturer has assessed the risk of liability of coming to market. To be penalized under the PMPRB Framework pursuant to an implied license would be unjust as it would not reflect the reality of the relationship between the patentee and the generic manufacturer.

Proposed Amendment to the PMPRB Framework

The mere purchase and sale of drug ingredients from a supplier should not be construed as a patent license in the context of the manufacture of generic drugs, subject to express patent license rights otherwise conferred.

The absence of patent litigation between a third party patentee and the generic manufacturer should not imply that there is a patent license between those parties.

The PMPRB Framework Should Set out the Excessive Pricing Analysis Applicable to Patented Generic Drugs

Section 85 of the *Patent Act* sets out the factors applicable for determining whether a drug product is priced excessively.

In considering the section 85 factors, for a Patented Generic Drug, the price of the corresponding brand drug alone should be used, and the prices of other corresponding generic drugs should be excluded. In short, all price comparisons, domestic and international, should be in relation to the corresponding Patented Brand Drug.

In respect of assessing excessive pricing, section 85(1)(d) refers to changes in the Consumer Price Index (CPI) as being one factor that should be taken into consideration; however, it should not be operative where the generic drug remains priced according to tiered pricing framework. Furthermore, CPI generally should not be a relevant factor in the consideration of whether generic drug prices are excessive, since generic prices tend to be fixed at the time of market entry, and do not benefit from annual CPI increases, but instead remain frozen in time for several years, and often decades.

In determining the price at which a Patented Generic Drug is sold, discounts and rebates to customers, wholesalers, and payers (including governments) would be taken into account. It is important to note that in the generic industry, discounts and rebates,

in provinces where permitted, are typically provided on a blended basis, namely across a basket of drug products. In other words, discounts and rebates are seldom provided on a product by product basis for generic drugs. As such, blended discounts/rebates across a basket of products should be accepted under the PMPRB Framework in the pricing analysis.

If the Patented Brand Drug is no longer on the market, then any price comparisons should be in respect of the last, highest available brand drug price.

Proposed Amendment to the PMPRB Framework

Section 85(1)(d) refers to changes in the Consumer Price Index as being a factor to be taken into consideration in respect of assessing excessive pricing. This factor should not be operative in relation to the analysis of Patented Generic Prices.

Blended discounts/rebates to customers, wholesalers, and payers (including governments), across a basket of products, should be expressly considered when making determinations under the excessive pricing analysis.

The PMPRB Framework Should Specify that Excessive Pricing for Patented Generic Drugs is Prospective Only

Given the regulatory uncertainty up to the present concerning the PMPRB's regulation of Patented Generic Drugs, and where patent licenses might be implied, for example, the PMPRB should only pursue excessive pricing matters, and associated penalties, in respect of Patented Generic Drugs that are introduced to the market subsequent to the issuance of the revised Guidelines (i.e. the PMPRB Guidelines should clarify that there will be no retroactivity in respect of excessive pricing for Patented Generic Drugs).

Proposed Amendment to the PMPRB Framework

There should be no retroactivity in respect of the PMPRB Framework in respect of Patented Generic Drugs.

The CGPA Emphasizes its Support for the Continued Monitoring of R&D Investment in Canada in Relation to Sales of Patented Brand Drugs

Section 89 of the *Patent Act* requires the PMPRB to provide a report to the Minister of Innovation, Science and Economic Development setting out, for example, research and development (R&D) investment in Canada made by brand manufacturers. As such, each year from 1988 onwards, the PMPRB has issued a report setting out data in respect of the ratio of R&D-to-domestic sales for Patented Brand Drugs. The Minister is required, under section 89(4) of the *Patent Act*, to cause a copy of the PMPRB report to be laid before Parliament.

Section 89 of the *Patent Act*, and related provisions of the PMPRB Framework, were implemented for reasons important to all Canadians. As described below, market monopoly rights were granted to brand manufacturers in exchange for a commitment by those manufacturers to invest 10% of the sales revenue of Patented Brand Drugs in R&D in Canada. In other words, the delayed generic drug market entry and higher drug costs paid by Canadians for Patented Brand Drugs were in exchange for dramatically increased R&D investment in Canada by brand manufacturers. Monitoring the amount of these R&D investments is valuable information for the federal government and for all Canadians: it is a measure of the value Canadians received and continue to receive (i.e. R&D investment in Canada) in exchange for delayed generic drug market entry.

By way of background, in the late 1960s, due to the federal government's concerns of high patented drug prices and low R&D investment in Canada by patent-holding brand manufacturers, the federal government strengthened the "compulsory licensing" regime under the *Patent Act*. Under the compulsory licensing regime, notwithstanding a patent for the brand drug product, generic drug manufacturers were permitted to import and sell patented drug products pursuant to these compulsory licenses in exchange for a license fee paid to the patent holder.

In 1987, amendments were made to the *Patent Act* as a result of Bill C-22. Those amendments: (i) diminished the scope of the compulsory licensing scheme, (ii) enabled patenting of pharmaceutical products themselves (i.e. rather than product by process patents alone), and (iii) established patent terms of 20 years from the date of filing (i.e. versus 17 years from date of issuance, previously). Bill C-22 also provided for the creation of the PMPRB itself. Further amendments to the *Patent Act* were implemented through Bill C-91 in 1993, which were triggered in part to comply with the requirements of NAFTA. The Bill C-91 amendments: (i) abolished the granting of compulsory licenses; and (ii) enabled the introduction of the *Patented Medicines (Notice of Compliance) Regulations*, which provided brand manufacturers the ability to delay the market entry of generic drug products by prohibiting the issuance of the notice of compliance for the generic drug pursuant to what is now a 24 month stay.

In return for these additional market monopoly rights for brand manufacturers and the consequent delay of generic drug market entry, brand manufacturers committed to boosting levels of R&D in Canada to 10% of sales by the end of 1996. The Annual Reports of the PMPRB demonstrate that brand manufacturers have failed to meet their R&D-to-sales ratio commitment since 2003. As set out in the 2015 Annual Report of the PMPRB, members of Innovative Medicines Canada (formerly Rx&D) spent only 4.9% of their annual revenue on R&D for the 2015 year. Furthermore, the PMPRB's 2015 Annual Report reveals that the ratio of R&D-to-domestic sales in Canada is the lowest of comparator countries (i.e. R&D investment is substantially higher in various European comparator countries and the U.S., as a percentage of sales revenue).

The PMPRB's monitoring of the ratio of R&D-to-domestic sales data in Canada, and comparisons to data for various comparator countries, is extremely important information for Canadians and the federal government in the context of future trade negotiations. This is because brand manufacturers committed to a specific level of R&D investment in Canada, namely 10% of sales of Patented Brand Drugs, in exchange for

various market monopoly rights and the consequent delay of generic drug entry. Going forward, as Canada negotiates future trade deals in which it is proposed that additional market monopoly rights are provided for Patented Brand Drugs, the federal government, and Canadians generally, should be armed with information regarding the level of R&D investment that is being made in exchange for existing and any future market monopoly rights afforded for Patented Brand Drugs. This data is particularly important given that R&D investment in Canada by brand manufacturers is dramatically less than that made by those manufacturers in various European comparator countries and the U.S. The value of existing and future market monopoly rights for Patented Brand Drugs must be considered in the context of what Canada and Canadians receive in exchange for the delay to generic drug market entry.

CONCLUSION

Thank you for reviewing this submission of the Canadian Generic Pharmaceutical Association with respect to the PMPRB Guideline Modernization Consultations. We trust that the PMPRB will see fit to develop and implement separate complaints-based guidelines for Patented Generic Drugs that will take into account the important information contained in this submission. The CGPA looks forward to meeting with the Board and PMPRB staff to review in greater detail.

APPENDIX 1: RESPONSES TO CERTAIN QUESTIONS SET OUT IN THE "PMPRB GUIDELINES MODERNIZATION DISCUSSION PAPER"

Set out below are select questions set out in the PMPRB Guidelines Modernization Discussion Paper and the industry's comments in respect of those questions.

1. What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example:

a. Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced?

b. Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?

c. In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada?

d. Conversely, if a drug's price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada?

e. What economic considerations should inform a determination of whether a drug is potentially excessively priced?

For Patented Generic Drugs and for the reasons set out herein, any price comparisons for Patented Generic Drugs should be in respect of the corresponding Patented Brand Product in Canada. This approach should also be taken to Patented Biosimilar Medicines.

2. Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?

Yes. Further, for the reasons set out herein, any price comparisons for Patented Generic Drugs should be in respect of the corresponding Patented Brand Product in Canada. This approach should also be taken to Patented Biosimilar Medicines.

3. In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?

For the reasons set out herein, CPI should not be a factor in excessive pricing analyses for Patented Generic Drugs. CPI should also not be a factor in excessive pricing analyses for Patented Biosimilar Medicines.

4. Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e. the US, the UK, Sweden, Switzerland, Germany, France and Italy)?

For the reasons set out herein, all price comparisons for Patented Generic Drugs should be in respect of the corresponding Patented Brand Product in Canada.

6. What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?

Patented Generic Drugs should comprise a separate category of product for the reasons set out herein, to enable differential treatment of Patented Generic Drugs as compared to products that are sold pursuant to a product monopoly and priced accordingly. Such a separate category would also recognize that Patented Generic Drugs are of low risk of excessive pricing, particularly when sold according to a tiered pricing framework under the pCPA. The PMPRB should also apply a similar approach to Patented Biosimilar Medicines.

7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?

Yes, and there should be little regulatory oversight of Patented Generic Drugs due to the tiered pricing framework under the pCPA. As the pCPA also has a robust price negotiation approach for biosimilar medicines, Patented Biosimilar Medicines should also have little regulatory oversight by the PMPRB.

8. Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?

Price decreases imposed on the brand product would have a corresponding impact on the provincial price regulation of generic drugs generally, including Patented Generic Drugs. This is because the prices for generic drugs are routinely set as a percentage of the corresponding brand drug price. This is an important consideration, as a dramatic drop in the price of the corresponding brand drug prior to generic entry could decrease the commercial viability of generic versions of the generic drug product at current generic drug pricing. In contrast, price increases or decreases of the brand drug subsequent to generic entry have no impact on generic pricing. The same is true for Patented Biosimilar Medicines.

9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?

No, not with respect to Patented Generic Drugs because the federal, provincial, and territorial governments have pooled their resources, through the pCPA, to regulate pricing of generic drugs, and there is now full federal/provincial/territorial participation in the pCPA. Generic drugs are the same price in both the public and private markets as regulated by the provincial formularies, so differential prices do not apply for different payer types in respect of generic drugs. Further, it would be an unnecessary burden to subject these same generic drug products to regulation under the PMPRB Framework. In addition, it could potentially put the two regimes into conflict whereby a generic drug is compliant with pCPA pricing, wherein the provinces have taken steps to ensure a stable drug supply, but non-compliant with PMPRB excessive pricing rules. It should also not apply to Patented Biosimilar Medicines.**10. Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?**

Please see the boxed text set out throughout this submission.

11. Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?

Given the regulatory uncertainty up to the present concerning the application of the PMPRB's Framework to Patented Generic Drugs, including in respect of where a patent license might be implied, the PMPRB should only pursue excessive pricing matters, and associated penalties, in respect of Patented Generic Drugs that are introduced to the market subsequent to the issuance of the revised Guidelines (i.e. the PMPRB Guidelines should clarify that there will be no retroactivity, and that the PMPRB will not pursue excessive pricing matters in respect of Patented Generic Drugs that are currently on the market).

12. Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?

The generic industry's preference is that the various proposed amendments to the PMPRB Framework set out herein be made at the level of regulation or legislation in order to provide appropriate predictability of the regulatory framework for generic drugs, including Patented Generic Drugs. This would be appropriate, given the low risk of excessive pricing of this category of drug product.

In any event, the exclusion of Patented Generic Drugs from the regulation of the PMPRB could be implemented by regulatory amendment, for example, including in respect of the excessive pricing analysis as per section 85(2).