PURDUE

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Patented Medicine Prices Review Board
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Submitted via email to: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

On behalf of Purdue Pharma (Canada), we offer our response to the PMPRB Draft Guidelines consultation which was initiated on November 21, 2019.

To begin, we state our support and alignment with other industry participants, national patient organizations, leading life sciences organizations and major provincial governments in opposition to the proposed regulations and draft Guidelines and echo their call **for the immediate suspension and re-evaluation of the entire PMPRB regulatory amendment process.**

Policy Context
As stated in our June 2017 response to the Minister of Health's discussion document entitled *Protecting Canadians from Excessive Drug Prices*, it is vital to meaningfully engage all stakeholders – governments, industry, academics, healthcare professionals and most importantly, patient and disease group representatives – in a robust discussion to modernize Canada's regime of price regulation of patented medicines.

The shared goal of this discussion, from our perspective, ***was and remains***, a modernized policy, legislative and administrative framework that ensures and improves broad, affordable and sustainable access to innovative prescription medicines on which millions of Canadians rely each day for their health and well-being.

This entire three-year process of attempted modernization of the PMPRB regime from policy intent to regulatory changes and now, new Guidelines, has been characterized by:

- Dismissal of legitimate concerns raised by a cross-section of stakeholders from industry, pharmacy, the life sciences ecosystem, patient advocates and provincial governments (notably Ontario and Quebec) such as:
    - The risk that Canadian patients will be denied access to new treatments in the future;

  - The risk of Canada losing its status as a Tier 1/Tier 2 country for new global product launches which will ultimately delay patient access to new medicines for several years;

  - A reduction of critical clinical trials activity in Canada: trials that drive higher patient survival rates across a range of diseases and save public payers more than $2 billion annually according to a 2016 Canadian Health Policy Institute study; and

  - Diminishment of biopharmaceutical sector revenues leading to reduced employment and significantly lower investments in R&D, plant, equipment and medical technologies, which ultimately impact federal and provincial revenues through the loss of personal and corporate income taxes;

- Ignoring successive PMPRB Annual Reports that reveal:

  - Canadian innovative drug prices, on average, have been flat or have increased by less than inflation since 1988; and
  - More than 75% of drug cost growth over the preceding five years is due to *increased utilization, not price changes*; and finally,

- The misalignment with the Government of Canada's Advisory Council on Economic Growth's recommendations to support Canada's Innovation Policy Framework that state, 'medical technologies' must be one of six critical economic sectors that government and industry seek to "identify regulations that are unnecessary, or over-burdensome, and suggest possible reforms" and "work to improve engagement between research and industry to achieve stronger commercialization outcomes."

Innovative Medicines Canada (IMC) Recommendations

Purdue Pharma (Canada) is proud member of Innovative Medicines Canada and abides by both the letter and spirit of the Innovative Medicines Canada *Code of Ethical Practices* in our daily interactions with all government and health system stakeholders.

We are supportive of the IMC response to this consultation and highlight several key elements of its submission, notably:

1) A proposed new regime that cannot be operationalized given numerous interpretation ambiguities surrounding the proposed new economic factors, a flawed maximum rebate price (MRP) concept, inadequacies in the protection of confidential business information and a lack of transition mechanisms for in-market medicines;

2) The substantive and irreconcilable difference between the economic assessments of the Government of Canada (a projected $8.8B NPV negative impact) and that prepared by a third-party expert for IMC (a projected $41.8B NPV negative impact); the latter assessment accounting for the full impact of the November 2019 proposed Guideline changes;

3) A need to provide technical working groups of PMPRB officials and industry representatives the ***appropriate and necessary*** time to generate an alternative Guidelines package consistent with core regulatory principles of feasibility, fairness, predictability and transparency;

4) The use of pharmacoeconomic evaluations from CADTH and INESSS to regulate excessive price ceilings being an extension of the role of the PMPRB beyond its current mandate as sanctioned by Parliament;

5) The lack of clarity with respect to the grandfathering (explored further below) of ALL existing products and any consequent transition periods for 'Gap' products; and

6) Numerous process concerns including the lack of an amended *Patentee Guide to Reporting*, lack of publication of detailed (not high-level) case studies on specific product scenarios, the massive IT and reporting changes incumbent upon Patentees subject to the PMPRB, and the recommendation notion of a lag between regulations/guidelines taking effect in law versus their actual implementation.

Purdue Pharma (Canada) Concerns

Our portfolio of patented medicines includes medicines used to treat pain, attention deficit hyperactivity disorder (ADHD) and chemotherapy-induced nausea and vomiting (CINV). We also in-license new drugs to benefit Canadian patients. Our portfolio of medicines is generally not in the category of so-called, high-priced drugs. Some of our medicines are widely-prescribed while others serve specific patient populations.

The proposed PMPRB guidelines, and their inherent ambiguity, increase the challenges of maintaining our current portfolio and complicate our ability to bring new and novel therapies for the benefit of Canadian patients.

Fairness and Openness: The concepts of "fairness" and "openness" are included in the current Compendium but not in the proposed Guidelines. We request that the PMPRB re-instate and meaningfully include the concepts of "fairness" and "openness" in its Guidelines as a basis for cooperation, compliance and to highlight what should be a shared objective of maximizing access to the best and appropriate medicines for all Canadians.

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Affordability Perception: With respect to affordability of medicines, it should be acknowledged that both public and private payers have been negotiating significant price rebates that are often confidential, and therefore, not visible to the public. In other cases, list prices are frozen, or increases are very limited – e.g. in Quebec, Alberta and Saskatchewan. These pricing pressures impact both patented and non-patented drug products and the simple use of list prices as a point of comparison underestimates the already present savings.

Discontinuations/Shortages: An unintended consequence of the proposed Guidelines could push list or transaction prices of in-market drug products lower and the resultant prices may only be the starting point for subsequent negotiation by payers. The combined impact from the drafted Guidelines and payer negotiations creates the danger of pricing being so low that supplying the Canadian market may become non-viable.

Median International Pricing Tests: Based on the drafted Guidelines, the median list price in the new basket of 11 countries will set one of the maximum price benchmarks for both exiting and new patented medications. Our recommendation is that this be modified so that Canadian prices are to be benchmarked relative to the highest international prices (HIP) in the basket.

The rationale for this is that two higher-priced reference countries (the U.S. and Switzerland) have been removed and six new lower-priced reference countries have been added in the new Regulations. Given that 10 of the 11 reference countries have lower drug price indices than Canada (i.e. only Germany is higher), the new basket using a HIP test would ensure that in many cases, Canadian list prices will be comparable to these low-priced reference nations.

One major issue with international price tests in general, is that in many of these countries, the reference prices are based on nationally-approved, negotiated reimbursement prices that ensure nation-wide market access for patients in these countries, while in Canada price approval by PMPRB and subsequent payer negation in no way guarantees access for Canadian patients.

To have this profound difference and still require that Canadian list prices be at the *median* is very problematic conceptually and in practice. As noted previously, there is a high risk that payers will still try to negotiate pricing well below the PMPRB maximum list price. The resultant depressed net prices could lead to discontinuations of current products or international decisions to delay or by-pass Canada for new drug products.

In fact, the new Regulations do not specify that a "median" test be applied. Median tests would have a dramatic impact on current and new product pricing. While we do not have such an extreme example in our portfolio, we have heard that prices of existing drugs could be pushed lower by as much as 90% based on median tests. Based on points made previously about supply of current drugs and access to new medicines, we urge you to reconsider application of a median test but instead institute a highest international price (HIP) test based on the new basket of 11 countries for new products.

Furthermore, reporting of Canadian list prices relative to foreign prices should be made with due consideration to what the prices represent – i.e. reimbursed access for patients in many comparator countries versus no access guarantee whatsoever in the context of Canadian PMPRB maximum prices. Because of the nature of the Canadian reimbursement landscape and confidential agreements, Canadian prices could be much lower. In any event, confidentially must be maintained.

As an example of the negative impact from *median* international and proposed domestic pricing comparisons, Purdue Pharma may have to abandon supporting a confidential project to bring a new drug product to Canada. One reason for this is that the international prices are low in the limited number of reference countries where it happens to be marketed. This combined with the potential inclusion of low-priced, older drugs in the domestic therapeutic class comparison calculations, would make the launch in Canada probably not viable. This product was planned to have a very low price – perhaps a few hundred dollars per year – yet it may not be viable based on the proposed Guidelines.

CPI and Price Increases: A clear relationship between pricing and the consumer price index (CPI) is a key concept in the old and new Regulations. The drafted Guidelines provide limited opportunity for a price increase – this does not seem to be in the spirit of the legislation. Over the course of a product lifecycle, inflation can significantly impact the cost to business; from ongoing regulatory requirements, product testing, manufacturing inputs, labour costs etc., the overall cost of maintaining a business and keeping high quality products on the market is not static. Therefore, all patented drugs should be afforded the opportunity to increase price by the change in CPI each year - and not only in certain circumstances as outlined in the draft. Historically over that last three decades, Canadian innovative drug prices have been flat or increased by less than the changes in CPI.

Discounts and Patient Support programs: There is still a lack of clarity from PMPRB on how discounts and/or product listing agreement (PLA) rebates will be reported and whether they will impact pricing over time. For existing products, it is our understanding that it will primarily be the *list price* that will be monitored and regulated. There appears to be a requirement for reporting PLA rebates or discounts, but we lack clarity as to how this data will be used and protected as it is confidential business information.

We need clarity and simplicity when it comes to how any discounts will impact price ceilings especially for existing, grandfathered drugs. The preferred and simplest solution would be for discounts / rebates not to negatively impact ceiling prices. IMC has also articulated confidentiality concerns over reporting discounts / rebates in light of signed agreements and competitive factors in the national and global marketplace.

"Grandfathering" Issues: There is a recognition that currently-marketed products are exempt from being reassessed using the new economic factors that are applied to Category I and II drugs. However, only some of the rules have been "grandfathered".

We are very concerned about the fate of our moderately-priced, compliant products currently on the market. Given that product pricing has already been impacted by confidential negotiated agreements in the marketplace, further price reductions could result in product discontinuations, drug shortages as priority of supply could be assured to other countries.

We request consideration to the following points for grandfathered products:

- Highest international price test and not the median;
- Clarity, fairness and status quo application of the Guidelines for currently-marketed, price compliant products;
- If there are any required price reductions, that they be transitioned slowly over time;
- Meaningful annual CPI price increases;
- The current $50K exemption per DIN be maintained;
- Flexibility afforded to line extensions:
    - Complex tests applied to line extensions could result in a new strength not coming to market;
    - Ensure a *simple* test to link the price of the new strength to existing strengths;
    - Allow an opportunity for flat pricing or low volume policy that could provide viability for low strengths to come to market – e.g. for pediatric use.

- More clarity required and timing concerns: Although we are only a few months away from implementation, there is still lack of clarity about exactly how existing products will be fully impacted. That is, it is not clear how ATPs for price compliant products will be used (if at all) to establish maximum allowable list prices. Also, in many provinces, list prices may be different than national list prices because of public plan regulations in those provinces – e.g. Quebec. List prices should not be forced down to the lowest level but should be allowed to remain in their currently compliant state (with a provision for yearly increases linked to CPI). The risk of not allowing for status quo on list prices, again, runs the risk of discontinuations or decisions by companies to forego coverage on certain formularies for economic reasons.

  We are concerned that there are a multitude of operational issues not yet clarified. Manufacturers need time to hear, digest and provide input into these issues as they not only impact their business but also access to medications for their patients. This situation reinforces the IMC point that an effective date of July 1, 2020 does not mean that implementation must occur on the same date.

New Products: The Canadian pharmaceutical market is fragmented and quite different than in other countries. Very often a new drug product is not accessible to many Canadian patients several years post approval by Health Canada. Once a drug is approved, companies must clear many hurdles – all of which frequently push prices lower and/or delay access for patients – i.e. PMPRB, CADTH, INESSS, the pan-Canadian Pharmaceutical Alliance (pCPA), provincial formularies and private plan reviews and access through “managed plans”.

This complexity and downward price pressure at each stage of this process will only be exacerbated and accelerated by the proposed Guidelines that will ultimately delay patient access, and in some cases, result in new medicines never coming to Canada.

Category I factors (PE, GDP and market size): The new factors that will be applied to new products are exceptionally complex and seem designed to push prices lower at every opportunity. For example, application of the market size factor for sales over $25M (based on pharmacoeconomic prices and unit sales) would push the per unit price lower on incremental sales. The formulas and scales seem arbitrary.

We are aware of difficulties by industry experts in reproducing the pharmacoeconomic analyses outlined in examples provided by PMPRB – this is just one concern associated with the complexity of the new factors.

Is there a basis and justification for price discounts being as high as 50% based on increasing dollar sales volume? Such significant discounts would most certainly discourage new product entrants. Conversely, will there be provision in the Guidelines for price *increases* as sales volumes fall? Several of our patented products have declining sales yet we are facing potential price decreases in the new Guidelines – that is, there is no provision for price relief as sales decline.

We are not suggesting that such a provision be necessarily added but rather the whole issue seems unnecessarily complex, seemingly arbitrary and a disincentive to bring new products to market. This would certainly have a negative impact on Canadian patients as the newest drug treatments may not be available to them.

These new factors are so complex and require so much external review, that manufacturers do not have any insight into what the potential price will be prior to deciding to bring a drug to Canada – i.e. *no predictability*. Pricing uncertainly only serves to delay or eliminate the possibility of a new drug coming to Canada.

We request that the new factors designed to push prices significantly lower be re-considered and simplified – ideally abandoned. For example, we are in receipt of the March 2019 PMPRB Working Group Report. It is a 285-page document full of complex economic and policy proposals. Based on this document and the drafted Guidelines, it seems impossible to pre-determine the resultant pricing – not even an approximation.

Companies have limited human and financial resources to determine the viability of products and future pricing under the new Guidelines. Again, the downward pricing pressures and complexity of the new factors are a significant disincentive to bring new drugs into Canada. We urge that the factors be significantly revised and simplified or abandoned entirely.

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Category II Therapeutic Class Comparison (TCC): The way this will be calculated is very problematic and will be a disincentive for new products that are *moderately-priced* and/or serve a smaller patient population to come to market. It appears that the drafted Guidelines propose that the median price of all domestic comparators (including generics), be used to set the price of the new medicine. To further push this price lower, the lowest list price for each comparator will be referenced, which may be the generic product or an older branded product which may have a reduced price to maintain some market share.

To compare an innovative new drug, with years of development and significant investment in clinical development to be compared to such products is bad health policy and fails to recognize innovation. This will only exacerbate the decline in new product availability in Canada. As an illustration, manufacturers of innovative products neither expect nor can they afford to be compared or priced relative to, for example, 30-year-old, potentially inferior products. Prices of such comparators may be eroded by 75% or even more.

Unfortunately, unless this provision is significantly revised (e.g. inclusion of generics and the concept of *median* price removed), we envision that manufacturers will not be offered a viable market for any innovative products. There will be little incentive to bring such products to market in Canada without any financial predictability or viability – especially when it can cost millions of dollars to get a drug product approved in Canada.

About Purdue Pharma (Canada)
Purdue Pharma (Canada) is a research-based pharmaceutical and consumer healthcare company which has operated in Canada for more than 60 years. Its employees are committed to improving the health and quality of life of Canadians. The company has a broad portfolio of prescription and non-prescription medications including: prescription treatments for pain, ADHD, chemotherapy-induced nausea and vomiting (CINV) and various ophthalmic conditions, as well as Consumer Health products. The company supports evidence-based education for the safe use of its products. Privately held and founded by physicians, Purdue Pharma (Canada) is independently associated with the worldwide Purdue/Napp/Mundipharma network of companies.

We thank you for considering the observations and recommendations we have made herein in response to your consultation documents. Should you have further questions, please do not hesitate to contact me directly at 905-421-3303 or grant.perry@purdue.ca.

Sincerely,

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