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Patented Medicine Prices Review Board (PMPRB)  
(Rethinking the Guidelines)  
[PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

Mr. Clark,

We are writing to you today to submit our feedback to the *PMPRB Guidelines Modernization: Discussion Paper* consultation.

We are a non-governmental organization in Yukon working in supporting people living with Hepatitis C in accessing health services and treatment.

The Hepatitis C world was radically changed recently by the advent of Direct Acting Antiviral (DAA's) that lead to a cure for almost everyone treated. Finally with these medicines available, we could potentially eliminate the virus in Canada.

The approval of these medicines and their subsequent entry to market drew attention to glaring weaknesses in Canada's legislative and regulatory systems surrounding the pricing of medicines in Canada. These systemic faults allowed DAA's to enter the market at prohibitive prices, leading to a rationing of treatment by payers who are unable to afford the cost to treat all of those in need.

This situation presents a clear picture of some of the areas of our legislative and structural system that require revision. The following are areas of the patent and pricing guidelines that require adjustment and review in order to enable the PMPRB to ensure that Canadians have access to patented medicines at affordable prices.

### ***Cost Effectiveness:***

Current cost-effectiveness analyses look primarily at the cost of treatment against the cost of no treatment on a patient-by-patient basis. When looked at this way, DAAs for HCV are cost-effective even at very high prices.

The problem with this equation arises when a drug has the potential to treat an illness that affects a large number of people such as the estimated 250,000 living with HCV in Canada.

### ***Our recommendation:***

- **The PMPRB must include factors such as the prevalence of an illness and the potential benefits to population-health when considering the cost-effectiveness and potential price of a drug.**

### ***International Price Comparisons:***

The countries that comprise of the PMPRB7 were selected because they modelled pharmaceutical Research and Development (R&D) levels sought in Canada. Several of these countries consistently pay among the highest prices in the world for drugs. Using these countries as comparators has led to Canadians routinely paying among the highest patented drug prices in the world. Canada's R&D levels have not increased as promised.

### ***Our recommendations:***

**When conducting an international examination of drug prices, Canada should look to countries who:**

- **are similar to Canada in factors such as in demographics, disease prevalence; budget and population health goals;**
- **have actual pharmaceutical R&D investments close to our own.**

### ***Domestic Price Comparisons:***

Currently any improvement upon previous treatments for an illness can lead to increasingly expensive drugs entering market. This practice is faulty in that it can lead to the presentation of incrementally improved drugs being priced at incrementally higher prices. In the case of recent breakthrough drugs for HCV, ceiling prices were established at higher prices than for the formerly best in class (already expensive) medicines that had been used to treat the illness. The massive improvement of the efficacy and reduction in toxicity of DAAs as compared to former HCV treatments meant the realistic prospect of treating all people living with HCV. Sadly, the high prices allowed for DAAs resulted in rationing of treatment and the establishment of strict eligibility restrictions being put in place by most payers.

A second difficulty in this practice is that prices being used for domestic comparisons are often not reflective of confidential discounts that have been established between industry and various payers. This leaves the PMPRB modelling to artificial prices thereby accepting inflated price ceilings for medicines.

**Our recommendations:**

- The cost of new, improved treatments should be evaluated based on factors beyond the benchmark price established with older treatments. Some of these factors should include the prevalence of an illness; and a treatment's potential contribution to the improvement of population health.
- When domestic price comparisons are used, it is essential that they be based on actual prices rather than on inflated price ceilings.

*Industry Transparency:*

The lack of transparency by pharmaceutical companies contributes to ineffective and inefficient drug pricing and access systems in the country.

**Our recommendations:**

- The PMPRB must work with Federal and Provincial/Territorial and international parties to address and reduce disparities created by a lack of drug pricing transparency by industry.
- The PMPRB should consider ways to drive down ceiling prices established at the introduction of a drug to market thereby establishing a most realistic price point at the onset and dissuading the negotiation of discounted prices.

*Ability to Re-Bench:*

There are situations under which established drug prices might require a re-examination. The PMPRB is currently limited in its ability to do this.

**Our recommendation:**

- The PMPRB should be empowered with the ability to 're-bench' and re-evaluate the appropriateness of a drug's price (periodically, or under other circumstances such as the revision of indications surrounding a medicine, a re-evaluation of the prevalence of an illness, or the establishment of improved disease management practices).

Addressing these factors will contribute to an improved drug pricing system that monitors and regulates drug prices keeping patients and population health top of mind. It is essential in this review that both transparency and flexibility be emphasized and ensured. We must be able to operate under guidelines that are fair, and that can be understood by all but that also are adaptable and able to respond to market and societal evolution and change.

We are encouraged by the PMPRB's level of engagement and openness in this process. We believe that your mandate is an important one and that the revision of legislation and guidelines will contribute to a strengthening of our country's ability to effectively enable access to medicines while protecting Canadians from over-pricing.

We appreciate this opportunity to submit our thoughts to this important consultation.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Bacon".

Patricia Bacon  
Executive Director  
Blood Ties Four Directions Centre