ACTION HEPATITIS CANADA

ACTION HÉPATITES CANADA

October 25, 2016

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

Mr. Clark,

I am writing to you today on behalf of Action Hepatitis Canada (AHC) in order to submit our feedback to the *PMPRB Guidelines Modernization: Discussion Paper* consultation. The AHC is a pan-Canadian coalition of 55 organizations working towards the elimination of viral hepatitis.

Identified in 1989, hepatitis C (HCV) is a leading cause of cirrhosis, liver cancer and liver transplantation in Canada. It is estimated that at least 250,000 Canadians are living with HCV.

We understand much more now about HCV than ever. It is preventable and it is curable. Advances in medicine mean that hepatitis C can now be cured in almost all cases in as little as 8 to 12 weeks. These new treatments - along with our knowledge about successful prevention practices - make the prospect of eliminating HCV in Canada a real possibility.

Even with this progress, nearly half of the Canadians who are living with HCV are unaware of their infection. Of those who are aware of their infection, too few are being treated to cure the disease. At these low rates of diagnosis and treatment, HCV rates will continue to rise.

The principle reason for both the low rates of diagnosis and treatment of HCV is that the cost of medicines are prohibitively high. Weaknesses in our legislative and regulatory pricing systems are largely to blame for these high costs. Systemic faults allowed DAAs to enter the market at exorbitant prices, leading to a rationing of treatment and a reluctance to diagnose by payers who are unable to afford the cost to treat all of those in need.

The situation presented by the advent of DAAs and the subsequent analysis of price 'acceptability' by the PMPRB presents a clear picture of some of the areas of our legislative and structural pricing system that are outdated and require revision. The following are areas of the patent and pricing guidelines that require adjustment and review in order to enable the PMPRB to fulfil their mandate ensuring 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 the PMPRB7 were selected because they modeled 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 yet 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 benching 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).**

We believe that addressing these factors will contribute to an improved drug pricing system that monitors and regulates prices prioritizing health and accessibility for those in need. We would like to emphasize the importance of patient involvement, transparency and flexibility as your department proceeds with the next stages of this review.

The revised guidelines resulting from this modernization process must be fair and easily understood by all. They must also be adaptable and able to respond to market and societal evolution and change as well as to new industry strategy as it emerges.

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,

Patricia Bacon
Chair, Action Hepatitis Canada

***Action Hepatitis Canada*** *is a national coalition of organizations responding to hepatitis B and C. Our work engages government, policy makers, and civil society across Canada to promote hepatitis B and C* ***prevention****, improve access to care and* ***treatment****, increase knowledge and innovation, create public health* ***awareness****, build health-professional capacity, and* ***support*** *community-based groups and initiatives.*