

Patient Group Input to
Patented Medicines Prices Review Board (PMPRB) of Govt. of Canada from
HepCBC Hepatitis C Education and Prevention Society (HepCBC)
February 14, 2020

Introduction

This report is a summary of HepCBC Hepatitis C Education and Prevention Society (HepCBC)'s feedback regarding upcoming changes to the Patented Medicines Prices Review Board (PMPRB) Guidelines. A HepCBC representative presented this feedback in person at a meeting with PMPRB officials in Vancouver on December 2, 2019. It draws on written input given to PMPRB by HepCBC on October 30, 2016 and June 28, 2017 as well as HepCBC's notes from the December 2, 2019 meeting. In this report, our registered charity is fulfilling part of its mandate, advocating for those living with or affected by hepatitis B or hepatitis C. Further information about our organization can be found at www.hepcbc.ca.

Background

While science is making headway by leaps and bounds, the economic engines of our country are not keeping pace. There are also increasingly competing demands on public dollars as our population ages and the number of people working declines. These problems are not unique to Canada but the federal/provincial/territorial split in our nation's health mandate is unique. HepCBC is particularly grateful to the researchers and others in academia, government, and the pharmaceutical companies who have made possible unprecedented leaps in the treatment of viral hepatitis, and want them all to continue finding new cures and treatments for other diseases. Yet, we must be able, as a nation, to afford these medicines. We applaud the attempt of PMPRB to address these huge systemic problems.

So we recognize there are many stakeholders here, and while we cannot claim to speak for every viral hepatitis patient in Canada, HepCBC wishes to share what is, from our experience, the general effect on viral hepatitis (B and C) patients of each of the changes to the Guidelines. At the end, we will share one further concern we hope can be addressed at a federal level.

I. Benchmarking prices against countries that are more like Canada economically and from a consumer price protection standpoint

We wish to sincerely applaud the updated schedule of comparator countries which deleted the USA and Switzerland, added 6 countries much closer to Canada in terms of similar consumer protection priorities, per capita and GDP wealth, and markets (Australia, Belgium, Japan, Netherlands, Norway and Spain), and kept the 5 original list's countries most similar to Canada (France, Germany, Italy, UK, and Sweden). This much-improved "Basket of 11 Comparator Countries" will make price-comparisons much more equitable for the Canadian pharmaceutical consumers.

Unfortunately, this improvement did not come soon enough to affect the pricing of either greatly-improved hepatitis C cures or marginally-improved hepatitis B treatments recently added to the formulary. We see use of the new comparator "Basket" only applies to new applicants (those who obtain a new DIN after the publication of these Amendments in the *Canada Gazette*, Part II). ***While we would prefer that the "Basket" be applied retroactively, we realize this is unlikely and therefore recommend that the PMPRB apply this "Basket" to any revision, patent-extension, or creation of incrementally small changes or improvements which result in a new or extended patent, or a new use for a medicine which could impact its market in Canada.***

We further recommend that all analyses done in support of these Regulations be made public.

II. Considering the value and the overall affordability of a medicine when setting maximum price

(a) Value for Money

While health costs have always been a large part of every provincial/territorial budget, the cost of the drug portion of the overall health budget is growing as we learn how to cure life-threatening diseases such as Hepatitis C with a short, intense, and very costly treatment; or manage other formerly-deadly diseases like Chronic Hepatitis B or HIV/AIDS with lifetime monitoring and treatment. These diseases ***disproportionately affect marginalized and 'working poor' populations***: the elderly, youth, prisoners, and users of intravenous/inhaled drugs, as well as many indigenous communities and immigrant groups from endemic countries.

Accordingly, the high cost of curing or treating these diseases is putting unsustainable stress on Canada's various public reimbursement plans as well as private insurers. While ***these treatments provide a pathway back to work and normal family life, decrease hospitalizations and the risk of early death, adding decades of quality life to so many, and decrease the chance of transmission of the disease to others, these tangible benefits to both individuals and society do not directly accrue to those doing the reimbursing***. Unfortunately we can see at least five costing "silos" here (pharma costs vs. hospital costs vs. lost-work costs vs. welfare costs vs. public health costs) which are related, but currently do not properly recognize savings in one silo (such as fewer hospital stays, fewer work absences, fewer people on disability or welfare, and fewer disease transmissions) due to spending in another silo (pharma costs).

We applaud the increase to a \$60,000 threshold cost per quality-adjusted life year (QALY) added by those high-cost medications (those with a cost that represents a significant share of the annual income of a typical Canadian). We also approve this increasing up to a \$90,000 (possibly more) threshold for rare diseases. Unfortunately we see that these requirements do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the *Canada Gazette*, Part II.

Again, while we would prefer that the new "QALY" pharmacoeconomic considerations and reporting be applied retroactively, we realize this is unlikely and therefore recommend that the PMPRB apply these considerations to any revision, patent-extension, or creation of incrementally small changes or improvements which result in a new or extended patent, or a new use for a medicine which could impact its market in Canada.

And again, we further recommend that all analyses done in support of these Regulations should be made public.

(b) Size of the Market

We suspect that miscalculation of potential market size in Canada may have been a major factor in the high cost of the new hepatitis C medications. Such drugs could actually have been priced much lower than they were because those who set the ceiling price did not accurately take into account the actual prevalence of the disease; neither did they predict the radical increase in demand which would result due to radically-increased efficacy combined with an almost total lack of side-effects, factors which would greatly affect the number of treatment packages sold. In these cases, there was no reason to allow "orphan drug" pricing for a conditions which had a large potential treatment population.

Very few people with hepatitis C were prescribed (nor wanted) the older treatments with extremely harsh adverse events and low efficacy; doctors advised most patients to wait for new, improved drugs (the 'warehousing' phenomenon). Once the new drugs became available, demand for them (coming from both medical practitioners and patients) skyrocketed. This might have been predicted by PMPRB if actual prevalence had been factored in as an economic metric. Note that this may have been complicated by the lack of accurate, up-to-date surveillance data showing how many people had chronic hepatitis C in Canada.

However, we recognize there is one huge factor which justifies a ***very different pricing structure between 'curable' vs. 'treatable' diseases***, the fact that if the medication is successful, the 'cured' patient will no longer need it, while the 'treated' patient will need it their entire life. R&D costs are likely similar for both types of medication, and these costs must be recovered in both cases. For this reason, a hepatitis C cure will always cost more per unit than a chronic hepatitis B (or an HIV) treatment. Hepatitis C patients understand and accept this rationale. However, ***once the R&D***

costs have been recovered, and reasonable profits made by shareholders, there seems little justification for continuing to charge such vastly-differing costs per unit, even for a ‘miracle cure’ such as the new hepatitis C drugs.

Again, we further recommend that all analyses done in support of these Regulations should be made public.

(c) GDP and GDP per capita

We see that “*medicines with costs that may occur within a 12-month period that would exceed a threshold of 50% of Canada’s GDP per capita* are subject to this reporting obligation.” This sounds like a very *reasonable point at which a drug’s pricing should be “flagged”* and investigated as possibly excessive.

While we have no objection to Canada considering GDP to determine an excessive ex-factory market entry price, we submit that including other measures such as overall percentage of dollar spent on prescription medicines relative to health outcomes, reduction of hospitalization or other metrics are also relevant and useful. Unfortunately, as stated in (II[b]), *the issue of silo budgeting, and looking at each piece of the health budget relative to outputs rather than holistically in relationship to their impact on health outcomes, is a serious fundamental flaw with our entire health care system vision and structure.*

We contend that GDP is one good comparator when selecting comparator-price countries, and that GDP per capita is a particularly useful figure when determining reasonable pricing. These factors are no more or less “volatile” than a factor such as QALY is “arbitrary”. None of the pharmaco-economic figures or formulae proposed are going to generate perfect solutions. But hopefully, taken together, they will enable PMPRB and manufacturers to greatly improve the current pharmaceutical pricing structure.

III. Regulating at the level of the actual prices being charged by patentees in Canada and not just the non-transparent manufacturer list prices.

We applaud this change, though confess to not knowing that much about this system.

IV. Reporting requirements

(a) Net revenues, and Patented OTC/veterinary/generics, and Pharmaco-economic info (cost-utility analyses from a publicly funded Canadian organization)

We have no experience nor any opinion on these matters.

(b) Market size information

As stated in (II[b]) above, market size should be a critical consideration in establishing pricing. *Factoring in prevalence as part of an economic metric for viral hepatitis (B and C), PMPRB will now require even more up-to-date and accurate epi-/prevalence data for viral hepatitis, something which Canada may need to prioritize (and budget for) in a federal strategy* for lowering our country’s pharmaceutical costs. *Broader screening and/or improved diagnostics* could be part of this strategy; this would fit in with Canada’s stated goal of eliminating viral hepatitis as a public health threat in this country by 2030, in accordance with World Health Organization (WHO)’s campaign. It would also identify potential ‘customers’ of a larger market for these drugs and related greater economies of scale.

Again, while we would prefer that the new market size considerations and reporting be applied retroactively, we realize this is unlikely and therefore recommend that the PMPRB apply market-size and prevalence considerations to any revision, patent-extension, or creation of incrementally small changes or improvements which result in a new or extended patent, or a new use for a medicine which could impact its market in Canada.

V. Additional Concern: Relationship between Research Costs and Generics

We would like to refer to Section 85 (3) the following subsection:

- “Research costs

(3) In determining under section 83 whether a medicine is being, or has been, sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

1993, c. 2, s. 7.”

We support strict enforcement of any law setting a minimum % amount of pharma R&D that a company is to spend in Canada. **However, we prefer that pharmaceutical companies be offered tax incentives for doing this rather than strict rules telling them what they must do, which are neither accurately monitored nor strictly enforced.**

We also acknowledge that R&D costs may be lower in other countries, so **requiring countries to do R&D in Canada may contribute to more costly drugs here, something patients do not generally like. At the same time, we do advocate for clinical trials to be held here in Canada.** Clinical trials held in other countries may not be representative of the Canadian landscape in terms of the diversity of genotypes, transmission routes, or other factors

Tying Canadian pharma R&D to pharma pricing has already been tried in Canada (in 1987 Patent Act legislation which still stands), and from everything we have seen, it has failed all around. The ‘carrot’ of relinquishing “compulsory licensing” in return for companies locating in Canada and contributing 10% of annual revenues to R&D in Canada was simply not attractive enough to pharma (compared to doing it in other countries), and we are now stuck with pharma contributing only 4% of annual revenues to R&D. At the same time our prices are still disproportionately higher, even than prices in Europe, and **Canada has given up (what had been) our sovereign right to invoke compulsory licensing (forcing pharma, before a patent has expired, to license generic version to be sold in Canada at much lower costs than patent drugs when deemed essential for Canadian public health).** Industry would probably like to see this expectation lowered or removed, and this is one area in which patient groups and industry would seem to be in agreement. **However lowering or even removing entirely the “R&D in Canada” expectations should be tied to reinstating that compulsory licensing can be invoked by Canada in certain cases.**

There are other R&D-related and similar considerations:

(a) Is the R&D actually being done in Canada, or in some other country? (This should be carefully monitored and publicly reported, presumably by PMPRB).

(b) How are the R&D dollars being spent in Canada – is the R&D being done disproportionately in one therapeutic class over others? (Canada could occasionally establish priority R&D areas in which they give tax incentives for R&D done in Canada for a specific therapeutic class that they feel is under-represented, or for research that Canada wants to see but that pharma may regard as non-lucrative. Examples could be a hepatitis C vaccine for IVDU or users of dialysis, or a combined hepatitis B/C oral Point-of-Care test for immigrants from endemic countries.)

(c) Is Canada giving tax incentives to companies according to what they spend on Canadian patients (i.e., in the form of compassionate care or co-pay rebates to individuals), in grants to Canadian researchers (in universities or small startups) or in grants to Canadian disease-specific physician, nurse, or patient groups?

Our general recommendations would be that **encouraging pharmaceutical R&D within Canada should be handled by Revenue Canada like any other incentivized investment, possibly in consultation with Health Canada or PMPRB. The current system would seem to be broken; and because it ties R&D in Canada to drug pricing (justifying not invoking compulsory licensing), it could be seen as contributing to our current high drug prices.**

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Thank you very much for this opportunity to give our feedback. HepCBC wishes PMPRB all the best in its efforts to create a more perfect pharmaceutical pricing structure for the good of all patients and their families in Canada.