

Recommendations on the Proposed Amendments to the Patented Medicines Regulations

February 14, 2018

Endorsed by:



Proposed Amendments to the Patented Medicines Regulations

Patient group response – February 2018

Introduction

In June 2017, a group of 18 Canadian patient organizations, mainly but not solely comprised of cancer groups, responded to the pre-consultation call for input from the Patented Medicine Prices Review Board (PMPRB) on proposed amendments to the Regulations to the Patent Act. The response submitted by the patient organizations, referred to hereafter as “we”, called on the federal government to ensure that there would be no unintended or unforeseen adverse consequences to Accessibility or Appropriate Use, the other two pillars of the federal health goals along with Affordability (the 3As), as a result of the proposed changes. In addition, we made many suggestions to address the issue of drug affordability underpinning the objectives of proposed changes. This patient group submission can be found here:

https://www.myelomacanada.ca/pixms/uploads/serve/ckeditor/pmprb_response_june_28_2017_final_endorsed.pdf

On December 2, 2017 Health Canada made public, in a [Scoping Paper](#)¹, the proposed changes to the PMPRB Regulations. The proposed changes are open to comments from Canadian citizen and interested stakeholders until February 14th.

The undersigned patient organizations believe that the patient voice must be heard on these proposed changes and are of the strong belief that, if enacted as proposed, the amendments may well result in:

- less access to necessary medicines for Canadians, either because fewer drugs will be launched or because, according to research published in a number of papers on similar pricing regulations enacted in other jurisdictions, there will be significantly longer delays in the launch of new drugs in Canada than presently.
- fewer clinical trials being made available to Canadian patients due to the adverse impact of the proposed changes on research incentives and investments.

Moreover the proposed changes made public on December 2nd do not address the concerns or recommendations we made in our June submission nor do they explain the flaws in the arguments made about the PMPRB proposed changes identified in our June recommendations. Finally the current proposals do not provide any concrete reassurance or monitoring process to Canadians that the availability of medications or access to

¹ <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1341>

clinical trials we currently benefit from, will not be jeopardized by the proposed regulatory changes.

We are seriously concerned that Canadians will, in fact, see a decline in innovative medicines access, which would drastically undermine the values we place in our healthcare system and the three pillars of the federal government’s health goals, i.e. the 3As.

On the one hand, the federal government does not accept there is a real risk for Canadians associated with the changes they are proposing. On the other, the industry, in meetings and the media, has indicated unequivocally that the proposed changes to the PMPRB Regulations will have a significant impact on availability of drugs and clinical trials for Canadians should they be implemented. Of course, we patients want to believe that this will not happen, but we are the ones being held hostage in this stand-off between government and industry. The government has a responsibility pursuant to its stated 3As goal of health outlined in the [Minister of Health Mandate letter](#)² to provide Canadians with a substantive plan to ensure that this does not happen before moving further with any changes.

We agree that the ‘modernization’ of the PMPRB patented drug price process is worth looking at, but so are the metrics associated with Research and Development investments made by the industry, which has been omitted in this most recent round of reviews. Government tends to take the position that research and development is not an important factor for patients and is solely an argument that industry should be making, however, research benefits patients in more than one way. This merits re-evaluation.

We also agree that Access, Affordability and Appropriate Use must be addressed in the context of sustainability of our health care system as well as integrating the value of new and effective treatments that have an important impact on Canadians quality of life, while maintaining consumer protection.

Lacking further clarification of the potential consequences of the proposed changes to the PMPRB Regulations as outlined in the Scoping Paper released in December 2017, we ask Health Canada to put the current regulation modernization process on hold until an open and fulsome consultation process between all parties including patient representatives affected by the drug pricing Regulations is undertaken so that better solutions to address the 3As can be evaluated properly and considered.

This is a high stakes issue for all of us!

² <https://pm.gc.ca/eng/minister-health-mandate-letter>

Specific Comments regarding the proposed changes to the PMPRB Regulations

1. Economic-based Price Regulations

Health Canada asserts that the introduction of new 'economic-based' PMPRB price regulations that include factors such as market size, cost-effectiveness, and Gross Domestic Product (GDP), would ensure that prices reflect Canadians' willingness and ability to pay for drugs that demonstrate better health outcomes.

This proposal conflates the concepts of price, cost and value. There are significant differences between these concepts with important implications for patients.

The jurisdiction of the PMPRB is to ensure non-excessive prices for drugs for sale in Canada. Economic-based health technology assessment on the other hand analyzes value, that is, the willingness of different payers in the system to purchase the product. PMPRB asserts that the willingness to pay is a direct result of price and therefore should be a significant and overriding factor in determining price. Elevating this factor to a special status above all others demonstrates an inaccurate assessment of how payers in the public and the private systems make decisions about what to purchase.

In the public system, the decision about value and what to pay for is based on an analysis of a number of many complex and discreet factors including the economic engine of the province, the size of the drug budget, size and demographics of the general population and people living with different diseases and disabilities. A price of a drug may not be excessive, but a payer may determine that it has other spending priorities given a finite budget. Of course, price is one factor that will determine how much they can purchase. Each jurisdiction (provincial/territorial governments, private insurers and individuals) is empowered to make its own decision on whether to pay for the value a medication brings to their constituents. The proposed economic based factors in the scoping document risk limiting access to some of the jurisdictions that may want to purchase a drug as it is proposing an all or nothing approach.

Private payers' decision about what to purchase is based on factors including the contractual needs of the clients, the size of the client and the other relevant demographic information about its workforce or membership.

The cost effectiveness test proposed is based on the advice of two highly competent Health Technology Assessment (HTA) agencies, the Canadian Agency for Drugs and Technologies in Health and the Institut Nationale d'Excellence en Santé et Services Sociaux, the advice of which is used by the federal, provincial and territorial negotiation

group, the pan-Canadian Pharmaceutical Alliance (CADTH, INESSS and pCPA) to address the value for money from a public payer's perspective. PMPRB is taking over the jurisdiction presently carried out on behalf of the provinces/territories by these very capable agencies to determine value rather than using factors relevant to excessive price. In addition to being beyond PMPRB's jurisdiction it is an unnecessary duplication and a waste of taxpayer money.

We recommend that all these health technology agencies (CADTH, INESSS and pCPA) should be consolidated into one body, responsible for determining access including cost-effectiveness, value and reimbursement schemes.

We submit that the inclusion of value-based on an HTA as a factor, and elevation of this factor to special status within the Regulations, are beyond PMPRB's excessive pricing powers as well as being an unnecessary duplication of resources from the current agencies involved.

In addition, we submit that all levels of government (Health Canada, CADTH, INESSS, pCPA and even the Canadian Association of Provincial Cancer Agency (CAPCA)) should align their efforts to produce one cost-effectiveness evaluation process to determine the value of a drug for patients and include all relevant factors including the patient perspective of value, not just leaving it to a Cost per (Quality Adjusted Life Years) QALY evaluation for the purpose of reimbursement decisions.

2. Choice of PMPRB comparator countries and ensuing consequences

The proposed comparator countries include: France, Germany, United Kingdom, Belgium, Netherlands, Italy, Spain, Sweden, Norway, Australia, Korea and Japan. Seven of them are new to the list i.e. Belgium, Netherlands, Spain, Norway, Australia, Japan and South Korea. We request an explanation as to why these seven new countries should be added to the list of 'comparator countries' along with the removal of Switzerland and the US. Given changes in global markets, there may be an argument to include new countries, but the government has failed to detail the rationale for the inclusion of these particular countries or why Canadians should believe these countries, especially the new ones, represent an appropriate comparator.

According to the PMPRB, using its proposed new list of comparator countries will have the effect of reducing the median price for drugs by approximately 20%. We believe this will result in unwanted consequences for Canadians by delaying launches of new drugs in Canada thereby limiting access to badly needed innovative medicines. Several international studies published in reputable journals internationally have concluded that

there is a detrimental impact on time to launch of drugs — even whether a drug is launched at all — when restrictive pricing policies have been introduced in the studied countries.

Has the federal government done its own reviews on the associated risks of the pricing policy changes they are proposing and will the federal government make these publically available?

How will Health Canada ensure that restrictive pricing policies will not delay the new therapies?

There are also other potential unintended negative ramifications of lowering the median price of drugs by using the proposed new list of countries. There is a risk that companies will wait to launch their new products until all 12 countries in the new comparator list have launched and have an established price, thereby delaying access to new drugs in Canada.

Data shows that Canada presently launches more drugs than most of the countries in the proposed list of comparators. For example, at the moment in two of proposed new comparator countries, Australia and South Korea, research shows that of all the drugs launched in Canada only 65% are launched in Australia and 54% in South Korea. This means that PMPRB is proposing to include countries where drugs are either not launched or launched at a later date than what we presently experience in Canada.³

Has Health Canada analyzed the average time to launch of these 12 countries compared to Canada and can Health Canada please make these data available?

Clearly, any delay in access to new drugs will not provide demonstrably better health outcomes as patients will have to wait longer to get access to valuable options to treat their disease. In some disease areas including oncology every day counts in accessing treatments toward survival.

3. Achieving lower costs

Public drug plans regularly negotiate lower list prices with manufacturers based on non-transparent criteria such as maximum cost, volume discounts, and evidence gathering to confirm effectiveness. We are concerned that lowering the price of entry of a drug in the Canadian market may reduce the amount a manufacturer can lower a negotiated reimbursement price with the provinces. PMPRB has expressed disbelief that this will

³ http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf

result from the Regulation changes while industry indicates that it will. The federal government has a responsibility to ensure that it has analyzed the potential impact accurately before moving ahead and makes its findings in this regard public.

Savings due to lower drug prices will certainly be transferred to the private plans and cash paying patients. There are no assurances from the private payers that these saving will be passed on to employers, employees or individuals insured.

We request that the government make public its analysis of where it will be saving 3.5 billion dollars as it has announced. We are unable to determine how this level of savings will be obtained within public plans.

We submit that more options such as pay for performance, risk sharing agreements, patient monitoring, adherence programs as well as stepping outside of the drug silo to look at how drugs are impacting other health care sectors should be developed as negotiating tactics for drug reimbursement. This will save far more than the proposed Regulation will do without restricting access.

4. Arbitration

The PMPRB has also indicated that updating the list of countries used for price consideration will be more aligned with their 'consumer protection mandate'. In our analysis, consumer protection is primarily needed with new breakthrough drugs given the price of subsequent-entry drugs are controlled by competitive market forces. PMPRB has also expressed this view.

We recommend that there be a binding arbitration process created for drug price disputes about excessive pricing in areas where there is a need for enhanced consumer protection but also an urgent patient need for access.

5. Patient voices

An important factor that is missing in the analysis is the value of a new health innovation as experienced by patients. If PMPRB is to include cost-effectiveness and QALYs in its evaluation, where is the patient input process associated with this review? CADTH and Health Canada have mechanisms and processes for the review of patient input. Since the "willingness to pay" aspect is important for PMPRB it should develop a patient input process based on different population perspectives, like the publicly and private covered patient population.

We urge PMPRB to ensure the patient input is captured and integrated in its review and encourage it to include this in a transparent manner.

6. Additional concerns

The proposed Regulations could negatively impact Canadians covered under private payer plans and individual payers. If a manufacturer decides that the new pricing framework is not in its best interest, it may delay launch or even choose not to sell the drug in the Canadian market. This would restrict access to needed medications for Canadians not covered under government plans even if they are willing to pay.

An important consideration that is omitted entirely from the proposed pricing review by PMPRB is the inclusion in the pricing process of the savings in other sectors of the health care system, e.g. hospitalization, side effect management, medical visits, into the pricing comparison. If a new treatment offsets the cost to the healthcare system it should be included in the factors being considered.

Solutions for consideration

We have been asked to suggest solutions and we are happy to provide some, while our list is rich in viable solutions other parties may also provide solutions worthy of consideration. Patient organizations in Canada understand the needs for the health care system to be more sustainable and agree with the federal Health Minister's strategy for health care reform based on the 3As: Affordability, Availability and Appropriate Use. The undersigned patient organizations made several recommendations in the original consultation document in June that focussed on a collaborative approach that would go a long way in solving the problems we are all facing.

Following are recommendations we believe offer concrete solutions to address the 3As.

1. Rather than the present Regulation changes that will potentially impede and reduce access to badly needed treatments, the federal government should engage the industry to develop strategies like the recently announced generic drug strategy in Ontario to ensure affordability. For example, a strategy for biosimilars would create considerable savings in the drug budget. These savings should be reinvested into the drug budget thereby enhancing access. The industry should also be required to provide funding for objective third party education that will enhance uptake of biosimilars as appropriate and will enhance appropriate use.

2. In determining value for HTA purposes, cost-effectiveness evaluation should be based on other measures than QALYs that are more patient-focused and genuinely represent patient needs. A value-based outcomes measurement system must be given a closer look by Canadian health authorities. A more useful question that should be addressed with respect to health technology assessment is how should its 30-year-old methodologies be modernized to best reflect Canadian's willingness to pay based on measured values of drugs in the real world.
3. All levels of government (Health Canada, CADTH, INESSS, pCPA and the Canadian Association of Provincial Cancer Agency (CAPCA)) should align their efforts to produce one cost-effectiveness evaluation process to determine the value of a drug for patients and include the patient perspective of value, not just leaving it to a Cost per (Quality Adjusted Life Years) QALY evaluation for reimbursement decisions.
4. pCPA should be mandated by the Council of the Federation to negotiate agreements based on such innovative contract approaches, pay for performance, risk-sharing agreements and other innovative contractual designs, rather than solely on negotiated price, since these approaches have been proven to reduce prices and the overall drug budget.
5. Companies should be required to offer a risk sharing or pay for performance formula for each negotiated drug and should be required to gather and analyze real world data for later reassessment after an agreed upon period on the market. Savings created will be reinvested into the drug budget. This will enhance access, affordability and appropriate prescribing.
6. Government policies should be created that ensure all savings from drug price negotiations are returned to the public health budget, or in the case of private group insurance plans, become an automatic rebate to employers for use to augment drug coverage for employees with life-threatening or serious illnesses.
7. Drugs for life-threatening diseases should receive special attention from payers. The federal government should not use any comparator countries that could delay market entry longer than Canada's present time to entry for drugs for life-threatening and other serious diseases or conditions. Canadian patients should not have to wait any longer than the existing lengthy delays to obtain access to badly needed treatments. Thus, some or all the comparator countries should be removed and replaced by more appropriate factors. The government should not use any comparator countries for drugs for life-threatening and serious diseases that have less clinical trial access as

clinical trials are an important means for access in Canada. A dispute resolution mechanism should be adopted to resolve disputes about the price for these drugs.

8. Adjustments on price must be based on the value that drugs bring to Canadian patients and thus be anchored in health outcomes measures, such as those obtained through Real World Evidence data generation. Pay for performance, outcomes-based criteria should only be used as factors to decide on willingness to pay. More resources should be placed in obtaining real world evidence to help adjust access policies

Comments on selected PMPRB Guidelines Scoping Paper questions

1- What consideration should PMPRB use in Screening drugs for high priority?

- Can PMPRB be more explicit with respect to what and how its review of clinical significance is different from the review already existing by Health Canada and CADTH?
- The GDP based threshold needs to be explained – Could this imply that the GDP factor may force the lowering of a drug price below the median of that of the basket of 12 comparator countries being proposed in the regulation changes.
- Market size is a significant issue for drugs to treat rare diseases, as the market will always be too small to allow for pricing that is in line with the value to patients, therefore jeopardizing the entry of these treatments in Canada.

2- To what extent should low priority drugs be scrutinized?

- Low priority drugs defined under the proposed changes to the PMPRB Regulations require more limited oversight. Under the proposed guidelines process the prices of these drugs would be reduced. When an innovator drug is 2nd or 3rd to come to market and offers equal benefits to the first entry, they are generally priced slightly lower than the first entry due to market forces. Moreover, the pCPA negotiation of low priority drugs would result in price being driven down.
- It is of grave concern that lower priority drugs may not be brought to the Canadian market by pharmaceutical companies should their entry price be reduced compared to the drug that preceded it. Not all drugs are the same, just like not all patients respond the same way to drugs of the same class.

3- Should the application of a threshold be subject to further adjustment depending on market size considerations?

- Market size assumptions are essential for any businesses as they bring a level of certainty and predictability on the size of the opportunity. This is true for any industry, including the pharmaceutical industry. It is not unexpected that

proposing market adjustment based on potential impact of a drug expected over three to five years introduces a level of uncertainty that companies may not be willing to accept, resulting in the decision not to launch or to delay launch in Canada.

- The argument around market size considerations as a factor for adjusting drug price presented in the PMPRB scoping paper assumes appropriate clinical utilization and no rationing of care. We know achieving this level of use is very much wishful thinking as the system is not perfect. The use of Real World Evidence data and treatment guidelines guided by the clinical evidence and pharmacoeconomic evidence (obtained through clinical trials and the collection of Real World Evidence generation) are much stronger factors.

4- How should re-benchmarking work and when should it occur (and to what drugs)?

- We believe “re-benchmarking” should occur as new drugs are developed and science to treat diseases advances.
- This process should be applied in conjunction with CADTH periodic class reviews and when a drug within a class has had the opportunity to deliver on its value for patients. This will ensure it is properly evaluated against other options within the same class. It is more about how a drug performs in comparison to best practices and how the best practices arsenal of drugs evolves over time.
- This process should be applied to several drugs within a therapeutic field as each drug within a therapeutic class and between classes must be sequenced to offer the most beneficial health outcomes to patients.

In conclusion, we submit that when looking at drug pricing policy changes, the federal government should do so in the context of overall health outcomes and the impact on the entire health care system. The real issue for many Canadians is lack of access or inadequate access to necessary medicines. As for lower-income Canadians, the primary concern is the lack of funds to buy drugs or the inability to pay the deductibles, co-pays and other costs associated with being uninsured or underinsured. It does not matter what the entry level price is for these Canadians. They simply cannot afford drugs and other basic living expenses. The federal government should set up a fund that lower-income Canadians can access to deal with this inequity in access. This is our definition of universal pharmacare.

The federal government must recognize that where the impact of lowering the drug entry price in Canada by 20 percent or more results in less access or delayed access for patients, the undersigned patient groups, and the patients and patients' families they represent will not support it.

We urge the federal government to show strong leadership by halting the current PMPRB regulatory change process and convening a multi-stakeholder group, including meaningful patient group representation, to find a shared vision for the health care system founded on value-based health outcomes and to achieve that goal together before moving ahead with any changes.

Respectfully submitted – February 14, 2018, by the following organizations:

- Canadian Arthritis Patient Alliance (CAPA)
- Canadian Cancer Survivor Network (CCSN)
- Canadian MPN Network
- Canadian Obesity Network
- Canadian Psoriasis Network
- Canadian Skin Patient Alliance (CSPA)
- Canadian Spondylitis Association (CSA)
- Canadian Treatment Action Council (CTAC)
- Carcinoid-NeuroEndocrine Tumour Society of Canada (CNETS)
- Cardiac Health Foundation of Canada
- Centre Associatif Polyvalent d'Aide Hépatite C (CAPAHC)
- Collective Oncology Network for Exchange, Cancer Care Innovation, Treatment Access and Education (CONNECTed)
- Colorectal Cancer Canada
- Kidney Cancer Canada
- Life-Saving Therapies Network
- Lung Cancer Canada
- Lymphoma Canada
- Melanoma Network of Canada
- Myeloma Canada
- Pancreatic Cancer Canada
- ReThinkBreastCancer
- Save Your Skin Foundation (SYSF)
- Schizophrenia Society of Ontario (SSO)
- Sickle Cell Awareness Group of Ontario (SCAGO)
- Team Finn Foundation
- The Canadian CML Network
- The Chronic Myelogenous Leukemia (CML) Society of Canada
- The Lung Association - Ontario