# PMPRB:

# A DUTY OF NEUTRALITY

The Canadian Organization for Rare Disorders commissioned me to research and write this memorandum to review machinery of government issues with respect to recently-released documents and communications by the Patented Medicine Prices Review Board.

The prime minister and his Cabinet colleagues shape the government's policy agenda. Ministers, in turn, are responsible for the policy direction and general administration of their departments.[1]

The Government has several machinery of government options whenever it decides to establish a new organization: departments, Crown corporations, agencies, boards, commissions and a quasi-judicial organization. Each organization falls within the portfolio of a minister, so that, he or she is accountable or answerable to Parliament. Accountable or answerable because ministers exercise varying degrees of control and responsibility depending on the organization.[2]

Ministers and their traditional line departments are called upon to speak on behalf of their departmental interests. It is expected, for example, that the Minister and officials in the Department of the Environment and Climate Change will be promoting the interests of their department and sector at the Cabinet table and before Canadians. The same is true for Veterans Affairs Canada, as it is for every government department.

There are instances, however, when the government decides that it is in the public interest to establish a distance between the political and the task at hand. Crown corporations, for example, are owned by the government but they operate at arm's length from the political arena because they operate in a commercial environment.

The government will also establish quasi-judicial regulatory agencies to generate impartial decisions and here independence is the way to get there.[3] A quasi-judicial organization is designed to operate away from political considerations to produce decisions that serve the broader public interest in a non-partisan manner. Quasi-judicial bodies are expected to strike decisions without paying attention to electoral or business cycles. In short, they are expected to provide a neutral perspective to ensure not only a level playing field but also to gain the confidence of all stakeholders.[4]

The Government of Canada explains that the Patented Medicine Prices Review Board is "an independent quasi-judicial body."[5] PMPRB is accordingly expected to operate outside direct executive supervision and generate decisions based on relevant and evidence-based assessments. It is expected to go about its work in a detached manner, relying on empirical evidence and not arriving at the table with a bias or predetermined position. The Government of Canada made this clear in its *Cabinet Directive on Regulatory Management*. It states that when regulating, the government will: "make decisions based on evidence and on the best available knowledge and science in Canada and worldwide."[6]

Quasi-judicial organizations have a Duty of Neutrality or *Un Droit de neutralité*. This implies that the organization should be neutral, free of influence and promote an attitude of neutrality in all its work and decisions. This is to secure the confidence of all parties interested in the organization and in its decisions. PMPRB should be no exception, which explains why the Government of Canada labels it "an independent quasi-judicial body with a regulatory mandate."

Questions are now being raised over PMPRB's approach and whether PMPRB is embracing *un Droit de neutralité*. The Canadian Organization for Rare Diseases (CORD) has gone public with its concerns. It made the point that PMPRB "never truly intended to consult on changes

to drug pricing regulations."[7] It pointed to PMPRB's communications plan to make the case what it labelled "a wide-ranging advocacy campaign that aims to amplify external stakeholders, target and support MPs and stakeholders who are aligned with the PMPRB's positions, while actively discrediting anyone who questions or criticizes them."[8] The President-CEO of CORD added: "I am so saddened that a regulator in Canada would request and budget public money to conduct a lobbying and advocacy campaign rather than engaging in constructive dialogue."

CORD is not the only stakeholder to raise concerns about PMPRB's approach. The Canadian Cystic Fibrosis Treatment Society has also expressed concerns. The Society wrote to the President of the Treasury Board to make the case that: "The regulator (PMPRB) now seeks to target, marginalize and de-legitimize the democratic patient voice." The letter adds that the "regulator is utilizing its resources and power to malign the very stakeholders it is supposed to protect."[9]

Both CORD and the Canadian Cystic Fibrosis Treatment Society are highly credible voices – they cannot be dismissed lightly and their concerns should give pause to policy makers in Ottawa.

PMPRB's communications plan raises questions about respecting the "Duty of Neutrality" expected of quasi-judicial bodies. I am attaching a PMPRB communications plan to make the point. The plan hardly paints a picture of a quasi-judicial agency that values a sense of detachment and a desire to go about its work free of any bias. I encourage the reader to have a careful read of the plan. Among other points, the plan argues that: the industry puts profits first and patients a distant second; they are knowingly disseminating false information; the industry is holding Canadians for ransom; the need to target supporters of the reform; identify stakeholders who are not fully supportive of the PMPRB and the list goes on.

The fact that more than one credible stakeholder has raised concerns, in a most forceful fashion, needs to be addressed. The Government of Canada has a clear policy on communications with the public. It reads: "provide timely, clear, objective, factual and non-partisan information" and "the government has a responsibility to communicate with Canadians to help protect their interests and well-being." This policy applies to all entities in the Government of Canada, and, to be sure, no less so for quasi-judicial bodies. It only takes a moment's reflection to appreciate that the Duty of Neutrality should be much more pronounced for quasi-judicial bodies than it is for standard government departments.

Stakeholders are not the only ones to raise questions about PMPRB's work and new regulations designed to regulate patented medicines sold in Canada. Nigel Rawson and John Adams, both with a deep knowledge of the sector, have produced a document that challenges the proposed regulations. It is worth quoting their paper at length: "Ottawa officials have blithely and falsely denied the negative impact of the new PMPRB regulations… The new rules are already having a disturbing effect on innovation for Canadian patients. Published case studies demonstrate that the new rules may require manufacturers to reduce prices to unsustainable levels. In addition, the numbers of new drugs approved in Canada and clinical trials funded by drug developers, which give desperate patients earlier access to promising therapies, have decreased. Between 2015 and 2020, the number of late-stage manufacturer-funded trials of therapeutic medicines fell by 22 percent in Canada, compared with only 11 percent in the United States. The overall decrease in Canada hides a 25 percent reduction in late-stage trials of non-oncology drugs between 2015 and 2020 and a 23 percent decrease in oncology trials between 2019 and 2020 after an increase of 20 percent between 2016 and 2019."[10]

At the risk of stating the obvious, it is the government of the day that proposes legislation and it is Parliament that has the final say. Legislation and regulations establish the perimeters within which public servants must operate. More to the point, they constitute a corset within which public servants need to operate. Accordingly, public servants are not free to improvise when they produce a communications plan or launch a strategic plan as PMPRB did for the 2015-2018 period.

All government entities also develop, over time, an organizational culture. These organizational cultures can and do differ within a government. The organization culture in Natural Resources likely differs from that in the Department of Environment and Climate Change or in a central agency from that found in a line department. They may differ but both need to align with their relevant legislation and regulations – in short, they need to operate within the legislation and regulations prescribed by the government and Parliament.

I decided to consult Wayne Critchley to see how PMPRB's organizational culture took shape. Mr. Critchley has a deep knowledge of the sector and played a pivotal role in shaping the organizational culture at PMPRB, serving as Executive Director from 1990 to 2005, or the agency's formative years.

Mr. Critchley explains that there was little difficulty in establishing an organizational culture at PMPRB to square with its legislative mandate. He adds: "we always knew there would be legal challenges, and we took a lot of pains to keep everything copacetic." He felt little pressure from politicians in his day to influence decisions. Everyone understood that PMPRB's success was tied at the hip to its ability to go about its work free of any bias, political or otherwise. He reports that PMPRB had a strong "track record of being upheld in the federal court on issues of bias in our processes."

But things are changing. PMPRB's Director of Policy and Economic Analysis, for example, wrote an email in late 2019 to colleagues that the "Industry has been sucking Canada for decades."[11] There has been and continues to be pressure on PMPRB to take sides. Mr. Critchley believes that PMPRB's reform proposal constitutes an "over-reach," a view that has also been upheld by the courts. The pressure on PMPRB to take sides will likely not attenuate in the years ahead.

However, from a machinery of government and given the requirements tied to a quasi-judicial agency, it will be important to ensure a non-bias perspective in PMPRB's work. If it is unable to both retain and promote this capacity in its work, its decisions will be challenged by one side or the other. This in turn will force stakeholders to spend time and resources to monitor the agency's work and subject PMPRB to continuing challenges. It would also violate a basic requirement of public administration – quasi-judicial agencies should go about their work free of any bias, political or otherwise.

Donald J. Savoie

June 7, 2021

**NOTES**

[1] There are, however, matters that are beyond the responsibilities of ministers – see, for example, the Financial Administration Act, and the Official Languages Act.

[2] Canada, Guide Book for Heads of Agencies: Operations, Structures and Responsibilities in the Federal Government, August 1999, https://www.canada.ca/en/privy-council/services/publications/guide-book-heads-agencies-operations-structures-responsibilities-federal-government.html.

[3] See, for example, Ian T.D. Thomson, *A Literature Review on Regulatory Independence in Canada's Energy System: Origins, Rationale and Key Features* (Ottawa: University of Ottawa, November 2020), 6.

[4] Ibid., 7.

[5] Canada, Patented Medicine Prices Review Board, undated, https://www.canada.ca/en/patented-medicine-prices-review.html.

[6] Canada, Acts and Regulations, "Cabinet Directive on Regulatory Management," undated, 4.

[7] "Worst Fears Confirmed! PMPRB Engages in Advocacy Campaign Against Patient," HRI Portal, May 26, 2021.

[8] Ibid., 2.

[9] Letter to the Honourable Jean-Yves Duclos from the Canadian Cystic Fibrosis Treatment Society dated May 24, 2021.

[10] Nigel S.B. Rawson and John Adams, *What Ottawa should do if it wants drugs and vaccines to be made in Canada and benefit patients* (Ottawa: Macdonald-Laurier Institute, 2021), 19.

[11] Quoted in "Is Ottawa prepared to call Big Pharma's bluff?," *The Globe and Mail*, June 4, 2021.

# Communications Plan

February 9, 2021

**Modern and Proactive Communication Strategy**

## Background

Since Health Canada's announcement of the coming into force of the amended Patented Medicines Regulations and the publication of the draft and final Guidelines (the "reforms"), the PMPRB's public visibility has increased dramatically. As such, opponents of the reforms have been more vocal about the potential negative impacts of their implementation and are spreading disinformation through organized public relation campaigns.

Although evidence does not support these claims, they appear to be gaining traction in the court of public opinion because they aim to strike fear in people, which is a very effective strategy and one that is difficult to refute through logic and responsive facts and figures,

## Issue

Pharmaceutical industry threats to withhold life saving drugs from Canada and human interest stories of Canadians suffering or dying because of lack of access to the latest breakthrough drugs occupy a large share of coverage in the media. The questions asked by MPs at HESA committee meetings demonstrate that opponents to these reforms have been effective at spreading disinformation. More recently there have been several articles that explicitly blame the PMPRB and its new Guidelines for delays or interruptions in the supply of COVID-19 vaccines.

Until now, the PMPRB has tended to use a reactive approach to the public relation campaigns of its opponents, with an emphasis on statistics and figures in its messaging.

## Objectives

- Accentuate the positive in telling the story about the PMPRB and its reforms.
- Improve the understanding of the human impact of the reforms
    - Ex: Our focus is to put your need first. Our goal is to prevent excessive prices so that all Canadians afford the drugs they need to live healthy and productive lives.
- Reinforce the PMPRB's commitment/importance to protecting Canadians against excessively priced drugs without affecting innovation or access to new medicines.
    - Ex: In order to support your needs, we need to make sure we have a health care system that is sustainable. The reforms ensure that we can afford and access the medicines we need at prices that are reasonable from both the consumer and manufacturer perspective.
- Highlight the benefits for Canadians of the reforms (e.g., savings will enable drug plans to pay for more and better drugs than they could otherwise).
    - Ex: Drugs are getting more and more expensive, thus leaving many Canadians unable to afford treatments for them or members of their family. Those costs are also putting pressure on our public and private drug plans that can no longer

cover all these important drugs. The reforms will allow savings that will enable us to pay for more and better drugs for all.

- Push back more aggressively and proactively on the industry's ongoing disinformation campaign.
    - Ex: Our focus is to put the need of Canadians first. The pharmaceutical industry's threat to withhold drugs from a market is a common tactic they have used with other countries during periods of drug pricing reform, and those countries still benefit from the same level of access as before despite having lower drug prices than Canada.
    - Ex: Despite what industry tells you, clinical trials and the number of new drugs coming to Canada have not gone down since the reforms were announced/adopted.

**Strategic considerations**

- With the most recent delay of the CiF of the amended Regulations, the prevailing narrative in the media appears to be that the industry has gained the upper hand in slowing/stopping the implementation of the PMPRB reforms. The industry is capitalizing on the additional delay period to ramp up its disinformation campaign and seek to engage the government in negotiations regarding a so-called alternative approach.
- The ongoing campaign has been echoed by some patient associations and other stakeholders who oppose the reforms in terms of disseminating disinformation on access and the possible impact on their respective patient constituencies. The CF community, CORD and the Best Medicines Coalition have aggressive public relation strategies that are aligned with the messaging promoted by the industry.
- Stakeholders who are supportive of the reforms are less vocal in the public sphere, thus, creating the impression that the public opinion is tilted against these efforts to lower patented drug prices.
- Changing the perception of the general population on the impact of the reforms after multiple years of lobbying by the industry will take time.
- The storyline of the cases brought forward by the mainstream media, patients associations and the industry focus on a human side, engaging a negative emotional reaction by the audience by appealing to their fears of being denied access to lifesaving medicines. PMPRB communications need to adjust to a more human-interest communication approach by focusing on the positive human impact of the price regulation.

**Target audience**

- Canadians – general public
- Stakeholders
    - Industry associations and representatives
    - Patient advocacy groups
    - Public and private payers
    - Non- and not-for-profit organizations
    - Academics
- Media
- MPs

**General key messages**

Access to drugs/putting Canadians first

- It is unacceptable that Canadians have to forego filling prescriptions for cost reasons while we pay among the highest drug prices in the developed world.
- Pharmaceutical companies sell to other countries around the world at much lower prices. Why should we pay more, especially if it means many Canadians can't currently afford the drugs they need to live healthy and productive lives?

Sustainability and balance

- Drugs are getting more and more expensive, thus leaving many Canadians unable to afford treatments for them or members of their family. Those costs are also putting pressure on our public and private drug plans that can no longer cover all these important drugs. The reforms will allow savings that will enable us to pay for more and better drugs for all.
- Our focus is to put the need of Canadians first. The pharmaceutical industry's threat to withhold drugs from a market is a common tactic they have used with other countries during periods of drug pricing reform, and those countries still benefit from better access to new drugs than Canada does, despite having lower drug prices than we do.
- In order to support your needs, we need to make sure we have a health care system that is sustainable. The reforms ensure that we can afford and access the medicines we need at prices that are reasonable from both the consumer and manufacturer perspective.

We listened

- For the past 5 years, we have sought and listened to feedback from all sides: you want affordable and accessible prescription drugs. The industry wants a fair return on its investments so companies can continue to research, develop, and sell medicines. Our Guidelines strike a balance between those competing objectives by gradually reducing the average prices of patented drugs by 6% over the next 10 years. These lower prices will mean more and better access to prescription drugs by making them more affordable while allowing the industry to enjoy the same level of profit it does in many other countries where prices are currently lower than in Canada and access is better.

Mythbusting/Did you know?

Clinical trial and R&D

- We have one of the lowest investment/number of clinical trials compared to our peer countries. In fact, many countries enjoy far greater levels of R&D investment and a clinical trials despite having considerably lower drug prices.

Drug prices

- Prescription drug prices in Canada are among the highest in the developed world. Why is the industry only willing to bring new drugs to Canada if we continue to pay such high prices?
- Don't fall for industry claims that clinical trials and the number of new drugs coming to Canada have gone down since the reforms were announced/adopted. They are knowingly disseminating false information.
- In threatening to withhold new drugs from Canada unless we continue to pay among the highest prices in the world, industry is holding Canadian patients for ransom. The industry puts profits first and patients a distant second, despite claims to the contrary.

**Specific key messages**
The mythbusting document will be used alongside the general key messages to generate specific answers to the disinformation. Those messages and associated facts and figures will be made available on the PMPRB website and promoted through various channels.

**Communications approach and tactics**

- Use a more human-interest approach when communicating to our key audiences.
- Use a more proactive communication approach to reach our target audiences.
- Promote, broadcast and repeat the general key messages in all communications, when feasible.
- Increase the use of social media:
    - Of the PMPRB twitter account to strengthen the understanding of the PMPRB messages while boosting the amount of followers
    - By creating a FB account to increase our reach to interest groups (patients, academics)
    - Challenge and refute misleading claims and dataCreate and maintain twitter feeds for the Executive and/or Chairperson
    - Present facts and figures to support the general key messages in a way that is more accessible to the public.
- Leverage the support and/or the understanding of the MPs on the pharmacare to increase awareness of the PMPRB mandate.
- Work more closely with stakeholders who are supportive of the reforms and encourage them to support our social media activity and be more vocal in expressing their support.

| Activities | Communication objectives | Who |
|---|---|---|
| Develop and promote main general key messages related to the disinformation | Increase the understanding of the general public on key areas where we found important disinformation | Comms |
| Social Media | | |
| Twitter: #DYD / #TBT | Increase the numbers of follower by using popular #<br>Increase awareness on the key areas where we found disinformation and provide accurate information<br>- Link to the DYK web page on the PMPRB | Comms |
| Twitter: answering tweets that promote disinformation on Twitter with accurate data | Providing facts supporting the main key messages | Lead : Comms<br>Support : P&EA |
| PMPRB FB account | Creating a new way to reach the general public | Comms |
| Research the # trends and using them more widely | Increase the PMPRB visibility in the public sphere | Comms |

| | | |
|---|---|---|
| Engagement through personal Twitter Account (Chairperson & Exec. Dir) | Extend the voices of supportive stakeholders of the reform by retweeting and commenting their public views/engagement. | Lead : Chairperson/Exec. Dir. Support : Comms |
| Web Site | | |
| New section "Did you know" on the PMPRB home page | Create a new web page where Canadians can easily access the 5 key messages and supportive data | Lead : Comms Support : P&EA |
| Other activities | | |
| Outreach to supportive stakeholders of the reforms | Coordinate communications efforts to improve the understanding of the reforms and to increase the audience. | Lead : Comms Support : P&EA |
| Promotional interactive PDF flyers | Ease the access to data and increase the understanding on the facts related to the key areas | Lead : Comms Support : P&EA |
| Thematic webinars | Present facts and figures to support the general key messages in a way that is more accessible to the public. | Lead : P&EA Support : Comms |
| MP kits<br>-flyers<br>-emails | Increase the understanding of the role of the PMPRB in the implementation of the pharmacare while promoting the key messages and its supportive data. | Lead : Comms Support : P&EA |
| Informative Video | Create and promote an informative video on the mandate of the PMPRB and how we operate. | Lead : Comms Support : P&EA |

**Budget**

Expecting expenses:
Flyers (6 000$)
Video (20 000$)
Webinar (30 000$)
Total: 56 000$

**Evaluation**

A thorough evaluation of each communications product and activity will be undertaken through various methods, including:

- Social media metrics (e.g., click-throughs, replies, re-tweets)

- Media monitoring (i.e., online, and broadcast)
- Public enquiries or feedback submitted to the PMPRB and Health Canada / Minister of Health
- Web metrics