



SUBMITTED VIA EMAIL: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

February 14, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

RE: PMPRB Guidelines Consultation

Dear PMPRB Board Members,

On behalf of several of Canada's leading provincial life sciences organizations in Alberta, Ontario and Quebec, we are writing this joint submission to the PMPRB Guidelines consultation to express our increasing concern regarding the recent changes to the federal patented medicine price controls.

Over the past two years, hundreds of life sciences stakeholders – including patients, life sciences organizations, researchers and medicine developers across Canada – have registered their concerns regarding the serious impacts for the future of Canadian healthcare and our innovation economy. These included serious impacts to economic investments and access to innovative, life-saving medicines for Canadians. These concerns have now been validated.

To help measure the impacts of the PMPRB changes, LSO engaged a third-party research firm to conduct an anonymous survey of Canadian and global life sciences leaders regarding how the PMPRB regulations will impact their operational, research, and commercialization plans in Canada (see full survey results below). Over 45 respondents took part in the survey, ranging from Canadian-based biopharma companies who want to sell innovations in Canada and globally to large multinational firms with significant operations and research initiatives in Canada.

Specifically:

- Nearly all respondents are aware of the PMPRB changes and forecast a negative impact (98%)
- Nearly all respondents foresee no launch or delayed launch decisions for Canada (94%)
- Nearly all respondents anticipate a decline in clinical trial activity and investment (91%)
- Nearly all respondents anticipate reduced employment in the life sciences sector (97%)
- Nearly three quarters indicated that the PMPRB changes will negatively impact patient support programs (73%) and reduce compassionate access programs (70%)
- The most impacted therapeutic areas will be in oncology, biologics, rare disorders, immunology, and gene/cell therapy – areas of the highest unmet medical need and where Canada currently excels globally in terms of science and research
- Companies are already making these decisions in advance of the implementation date

The use of economic factors and the resulting uncertainty is a major cause for concern among those surveyed. The application of these factors is ambiguous and leaves many questions unanswered. Companies need clear rules of engagement to guide their business decisions.

As it stands, there is no way to reliably predict the final list and net prices for medicines, which also makes the return on investment highly uncertain. This in turn makes it difficult for companies to make a compelling business case to prioritize the Canadian market for new medicine launches and investments in clinical research, patient support initiatives, and compassionate access programs.

The new basket of comparator countries used by the PMPRB will produce an average, across-the-board price drop of least 20%, which is already a substantial reduction, but it is at least predictable and easy to understand.

The application of the economic criteria are subjective and untested measures that will reduce prices even further – likely 40-70% below the current regulation limits based on the PMPRB’s case studies. No company or industry can absorb such a drastic hit to their revenues and continue to operate business as usual. Industry investments in Canada will be cut. Jobs will be lost. New medicines will no longer be available to Canadian patients.

For patients and the thousands of Canadians working to save and improve lives everywhere, our organizations strongly recommend that the PMPRB:

- 1) Pause the implementation of its Draft Guidelines indefinitely until these outstanding issues have been resolved
- 2) Recruit a third-party organization to conduct a thorough analysis of the current and potential impacts of the reforms
- 3) Work with stakeholders to develop and contribute to a more pragmatic approach to achieving the federal government’s desired goal of improving medication affordability

Sincerely,



Jason Field
President & CEO
Life Sciences Ontario



Frank Béraud
Président-directeur général & CEO
Montréal InVivo



Robb Stoddard
President & CEO
BioAlberta



Carl Viel
President & CEO
Québec International





Impact of PMPRB Pricing Changes

Final Research Report

February 3, 2020

Research  etc.

Background

Recently, the Canadian federal government passed regulations that change how the **Patented Medicine Prices Review Board (PMPRB)** will regulate maximum prices for patented medicines for every sale in Canada, which will come into force on July 1, 2020.

The regulatory changes include **revisions to the basket of comparator countries** (removing the US and Switzerland and adding six jurisdictions with lower-than-Canadian average list prices) and mandating the PMPRB to use **new economic factors** in its regulatory determinations (cost-per QALY thresholds and price reductions based on market size).

Life Sciences Ontario (LSO) commissioned a research study to better understand the **impact of these changes** on the pharmaceutical industry and life sciences organizations.

Three Key Research Objectives

1. **Understand awareness of and reaction** to upcoming changes to price controls in Canada among key decision-makers
2. **Determine likely response** to Canadian price control reforms, including any expected changes in business decisions and investments in Canada
3. **Confirm or refute the hypothesis** that the new pricing regime will have no negative impacts on access to medicines and investments in Canada

Methodology



STEP 1: Quantitative research

N=46 completes

5-minute online survey with decision-makers

Fielded Nov 19, 2019 to January 17, 2020



STEP 2: Qualitative research

N=10 completes

30-minute follow up in-depth telephone interviews (IDIs)

Fielded January 21 to January 31, 2020

Quantitative Sample Profile

N=36 Senior Pharmaceutical Executives (Presidents, GMs, EVPs, Director level)

- N=27 Canadian affiliate of a global company
- N=6 Parent company based outside Canada
- N=3 Parent company based in Canada

N=10 Life Sciences Executives

- Includes clinical trials, patient support programs, IT for healthcare, non-profits

Qualitative Deep Dive with ...

N=6 Large Global pharma companies

N=4 Smaller companies, including Canadian-owned and headquartered

PMPRB changes is the “#1 topic” among senior executives right now

98%

of survey respondents said they are **familiar** with the new PMPRB changes

83%

of pharmaceutical executives said they were “**very familiar**”

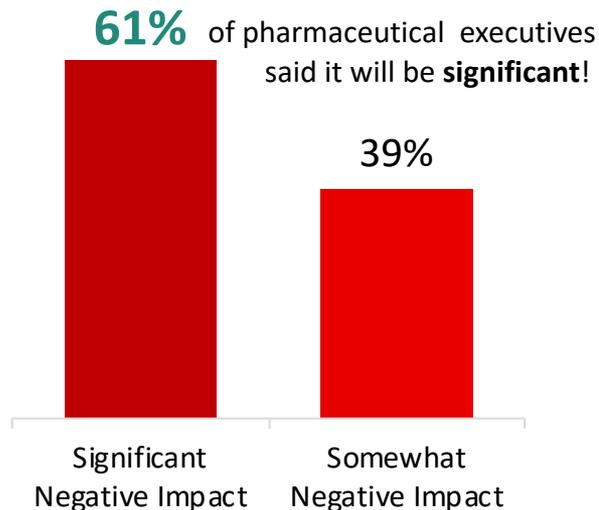
“
The single most prominent issue of our time.
I have been in the industry for 19 years, there has never been an issue that generated this level of concern.
It’s a preoccupation in Canada but also in Global boardrooms.
”

Q1. Overall, how familiar are you with the new PMPRB changes? (5-point scale: very familiar to not at all familiar) Base=46

Findings refute the hypothesis that changes will have no negative impacts to business investments in Canada

100%

of pharmaceutical executives said PMPRB changes would have a **negative impact** on their overall business plans in Canada



Impacts are already felt by both larger Global and smaller Canadian companies

“

We are a small Canadian company; we have already been impacted, putting product extensions on hold because of the uncertainty.

Our Global CEO visited Canada and articulated he doesn't see Canada in the same way. There are trust issues... Now we are seeing delays in decisions for Canada.

”

Similar high results for Life Sciences executives with 80% indicating negative impact

Q2. Please indicate the level of impact that the PMPRB changes will have on your plans in Canada? (5-point scale: significant positive impact to significant negative impact) Base=46 “N/A” excluded from the analysis

Executives explain PMPRB changes on business decisions

WHY?

are the impacts expected to be so profound?

Lower pricing + higher uncertainty = unfavourable market conditions

“

New guidelines want to put us in the middle of international pricing but [PMPRB] doesn't realize that you can't have that with the deeper public discounts we already provide and also apply the economic factor – this will put us at the lower end with Poland and Turkey which do not have access to new medicines.

”

“

It's January and in 6 short months these guidelines are supposed to come into effect. The economic factor is not known, it's hard to forecast and leaves us in an ambiguous place. When we consult with government, they don't have the answers, and it's leaving us confused.

”

Executives explain the need for market certainty

WHY?

are the impacts expected to be so profound?

\$1M-

\$2.5M

investment requires ROI certainty

“Our ROI is highly uncertain”

“

At a basic level if you want to launch a new product into the market, with regulation filing, the cost to go through Health Canada and pricing review, etc. it's \$1 million to \$2.5 million investment. That's an investment with 100% certainty of costs. Now it's hard to predict if the investments will produce revenues because of uncertainty.

”

Executives put Canada in context with global decision-making

WHY?

are the impacts expected to be so profound?



“Canada is a small player”

“

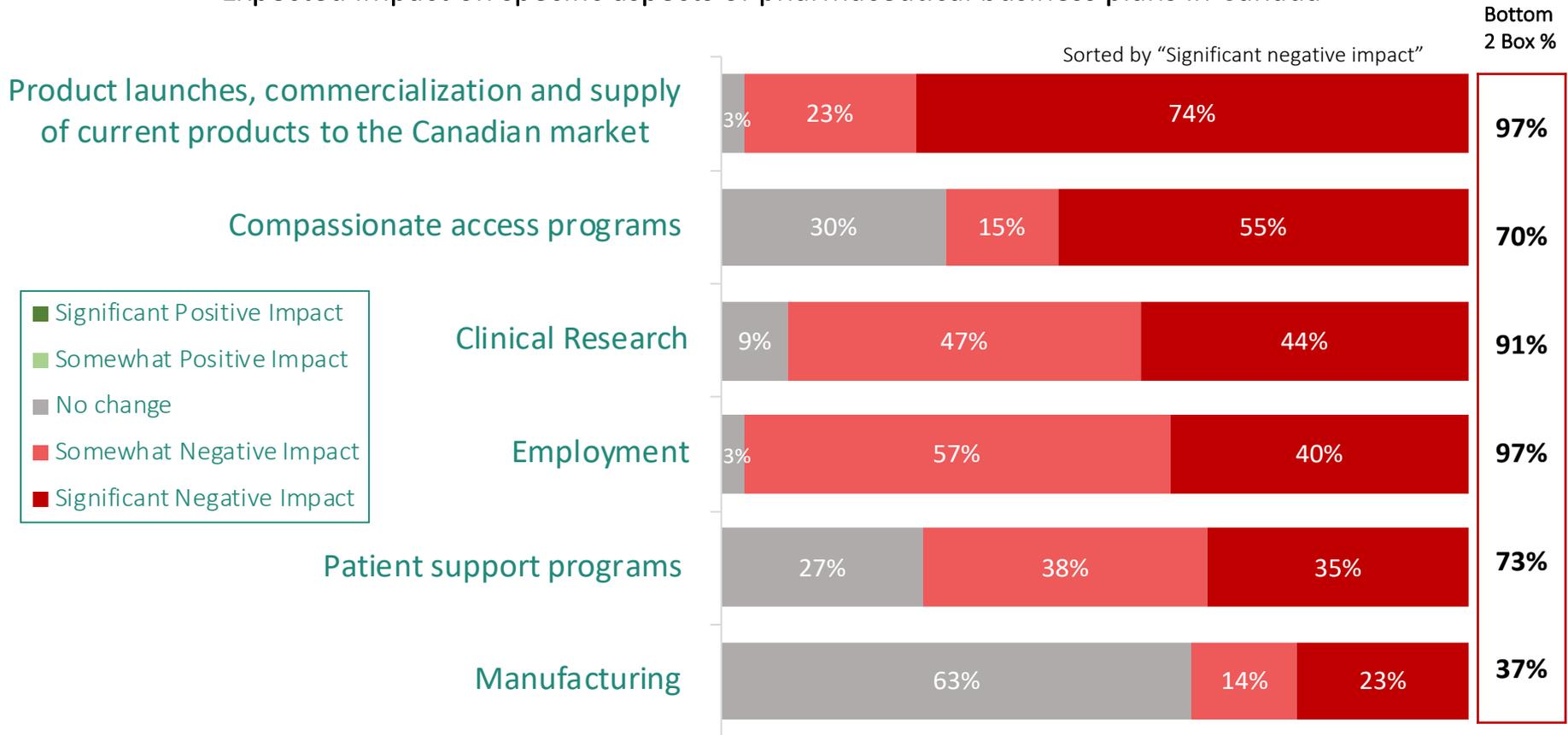
Canada is a reference country in other markets and prices in Canada have an impact elsewhere in the world. Most of these markets are much larger than Canada and innovators will sacrifice the Canadian market to be able to retain value in the other markets.

Canada is 2% of the global market. The US is 50%. We are not going to risk the rest of the world for the sake of Canada.

”

Pharmaceutical executives expect impacts across business

Expected Impact on specific aspects of pharmaceutical business plans in Canada



Q2. Please indicate the level of impact that the PMPRB changes will have on your plans in Canada? (5-point scale: significant positive impact to significant negative impact) Base=36 Only pharmaceutical executives asked (not Life Sciences Orgs) "N/A" excluded from the analysis

PMPRB changes expected to have a “cascade effect”

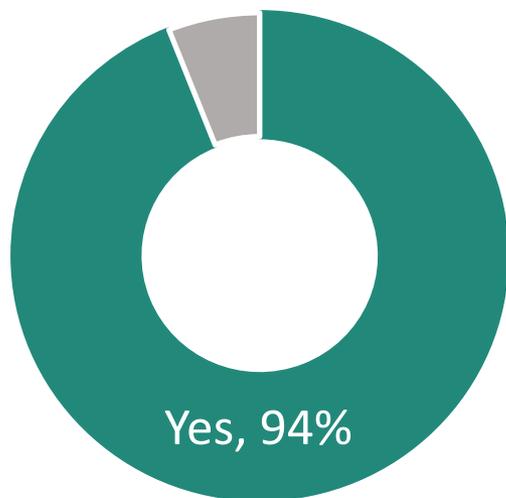


One pharmaceutical executive explained a “cascade effect” starting with delays around product launches ...

“ We intended to launch a new medicine in early 2021. Now that it’s clear our price will be dramatically reduced, we suspended our regulatory submission because the original business case and pricing assumptions have been challenged. ... It has a compounding problem, if not launched in a timely way, it will have impacts on staffing, training, hiring support, patient programs, etc. ”

PMPRB changes will negatively impact product launches

Almost all pharmaceutical executives foresee both delays and no launch decisions



1-3 years

typically cited as expected delay

“ Potentially 1-3 years based on the impact of Canada's price in other country's reference based pricing framework. ”

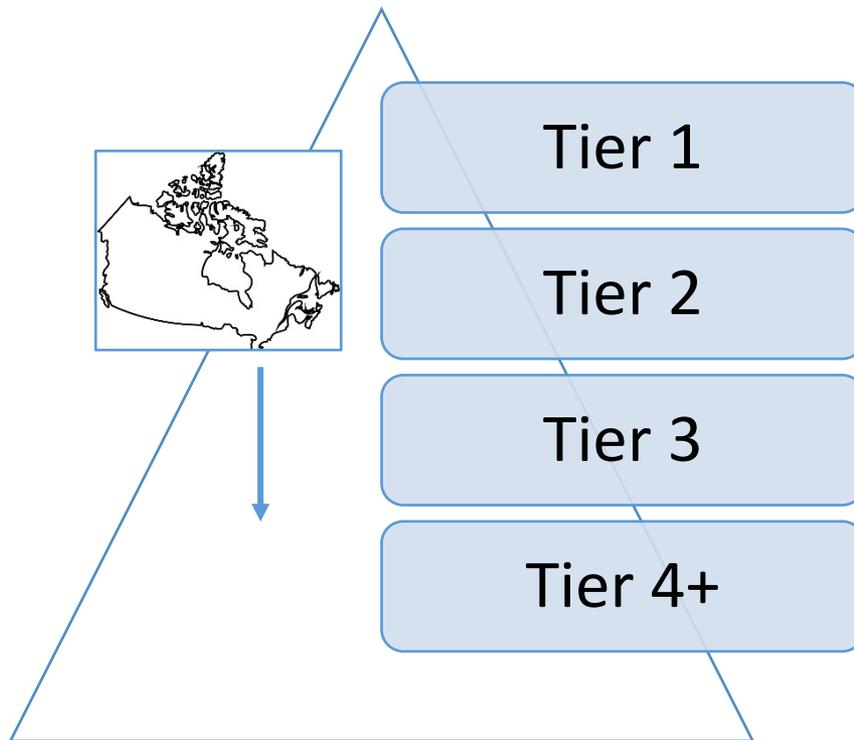
No launch

“ More decisions will be made to not launch at all vs delay because of the potential for broader harm to other larger markets. ”

Q4. Do you foresee any of the following? “No launch” decisions for medicines in Canada? Delayed launches for medicines in Canada? (Yes/No), Base=36. If yes to delay, by how many months? Base=36

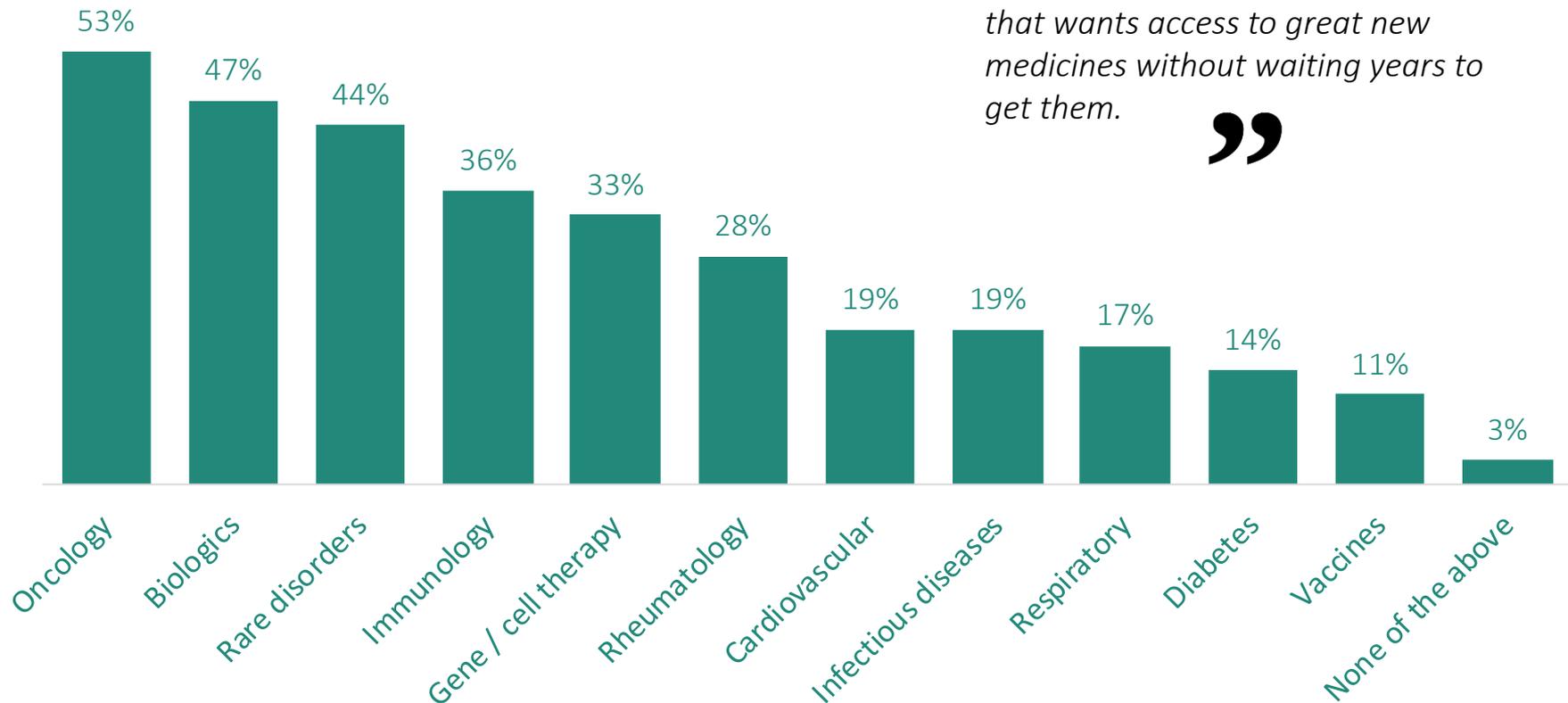
Impact on Canada's position globally

Pharmaceutical executives explain how PMPRB changes will impact Canada's global launch position



“ A lot of companies have tiered launch waves. Canada was always considered a Tier 1 or 2 country, launched either with or just after US, Germany, UK, etc. ...
Now it will be several years later since there will be access challenges before you even get to reimbursement. We will move down to Tier 3 or 4, or even worse, not launched at all. ”

Several therapeutic areas are likely to be impacted



“ Rare diseases come immediately to mind ... but it’s really any patient that wants access to great new medicines without waiting years to get them. ”

Q5. Which of your therapeutic areas in Canada, if any, are likely to be impacted as a result of the new PMPRB changes?
Base=36

Everyday Canadians should care about this issue

“

It goes to the heart of what we are here to do which is to ensure Canadians can access our medicines. It will significantly affect our ability to launch and launch in a timely way.

It's a shame that at this time where we now have truly revolutionary products such as potentially curing lung cancer that 5 years ago would have been unthinkable, that it's at this time the Canadian government is making a stand – right when we are at a tipping point. They see it as a budget issue but now we have personalized medicine and they don't even want to pay for testing. It's narrow thinking and it's wrong.

We are an ethical company. If we have a life saving product, it will be available in some form. But if it's not acute, not life and death, more chronic then there will be delays or reduction in choices. Only the sickest of the sick will get access. They are forcing us to make decisions we do not want to make.

”

Life sciences executives explain impacts on hospitals & patients

“

Many of our out of hospital support programs will be negatively impacted if prices are rolled back or reduced (infusion clinics) which mean closures and increased wait times at hospitals.

Changes will reduce the number of innovative products available in Canada and over time impact Canada's place in the global pharmaceutical industry. This will impact clinical trials groups, opportunities for new graduates and patients.

The proposed changes to pricing of specialty and rare disease drugs can translate to reduced investment in vital and value-added patient support services for patients and will ultimately reduce access to life-saving treatment for these patients. The changes will also impact patients as manufacturers will not be able to offer the same assistance and support to patients through patient support services to patients.

”

Micro to Macro Impacts on Canada



“ Canada is 2%-2.5% of the world’s pharmaceutical market. It will drop to 1%-1.5%, essentially cut in half because of PMPRB. Launching product in Canada is less attractive

There will be more layoffs, less investments, and fewer smaller companies going forward ”

“ We are different from bigger companies: we develop products here and have manufacturing and R&D here. If we don’t launch here, the future of our company is at stake. ”

We employ **250 high paying employees** in Quebec alone, 35% are PhDs and 60% Masters, all tax payers. PMPRB threatens them plus another **300-400 suppliers** which is 500-600 jobs in the next 3 years in Quebec alone, not to mention the impact on their families.

Final message to the Canadian Government

If you could only communicate one thing to the Canadian government about their intended PMPRB changes, what would it be?

Unless you change these regulations, you will be hurting Canadian patients indefinitely. This harms patients – full stop.

It's a tragedy of this proposal that these policy proposals will create a great deal of problems for patients and for companies but won't save money for the government.

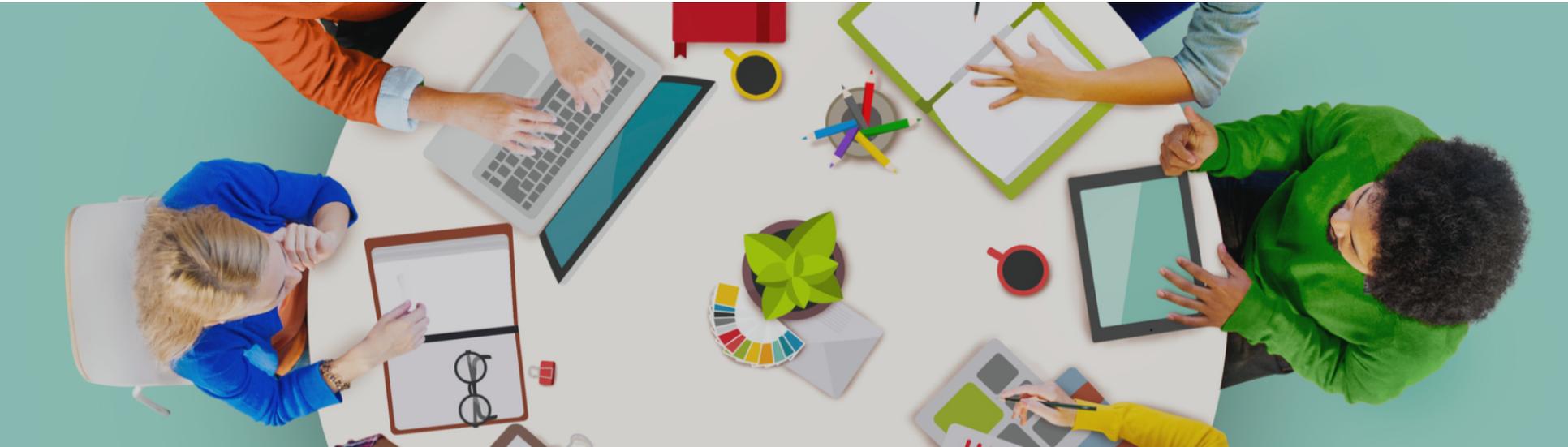
Changes are needed but they need to be well-planned. This is not well-planned and there is no time for transition.



**Government
of Canada**

Be careful what you ask for and the consequences you get. You worked to make PMPRB relevant. You need to understand the consequences.

A good solution can only be done collaboratively between regulators and those providing the medicines. This is too blunt an instrument and will hurt patients.



Thank you!

Rachelle Deshaies | rachelle@researchetc.com | 1.416.845.8565

Research  etc.

Business realities: Additional verbatim

We estimate a 75% reduction in price for [one] of our medicines.

We are small and don't have the scale of big manufacturers to compete. This is adding another challenge to a challenging industry.

Globally we invest 25% in revenue to R&D. If we take 25% reduction or more in revenue, we have to relook at investments – researchers, vendors, suppliers, employment across the board.

Through case studies, price reductions would be 40-70% and no impact on jobs or investment. It's disingenuous to believe this – how can any industry withstand that kind of reduction?

We will need to remove a key revenue generating product, and first line treatment option in its therapeutic class, from the Canadian market as a result of the changes. The new price we will be required to charge is below our cost of goods.

No/ Delayed product launch: Additional verbatim

Some products will not be launched at all in Canada. Even upcoming indications of currently approved products may not be launched in Canada.

Due to these pricing changes, Canada will likely be considered later in the launch sequence of countries, if at all.

We already have major challenges convincing our global headquarters to invest in Canada because it takes very long to get public reimbursement, but now we also have this great uncertainty about prices. I am afraid Canada will lose its place as a preferred country to launch new products - that's bad for us and bad for patients.

We are planning to delay the launch of [a new medicine] from 2020 to 2021 and perhaps until 2022. If we cannot get an acceptable price, then we will not launch the product in Canada despite the significant investments made by the company in Canada. Furthermore, our early access program for this medication is not likely to start. Canada is not a favorable launch environment at this point.

We have delayed launch of two significant innovative products due to uncertainty around the regulatory environment and the lack of predictability and stability around establishing a fair price in Canada. With no new products coming to Canada, planned significant expansion has been halted.

Verbatim from written survey responses from N=36 respondents as well as insights from Qualitative IDIs with N=10 pharmaceutical executives

Clinical trials: Additional verbatim

Will not do clinical trials for risk of having to keep patients on therapy in perpetuity without prospects of reimbursement at an acceptable price.

This will also affect the number of clinical trials we will be able to attract to Canada.

Is it ethical to expose patients to clinical studies if the company's product might not make it here?

These regulatory changes will negatively impact the world-class clinical trial network developed in Canada and will limit our industry's ability to invest in innovative R&D and high value jobs in the life science sector.

We have operations around the world and chose where to conduct clinical trials. We select accommodating environments. Canada is deemed a "bad market". It's a mess right now. Same applies to manufacturing.

February 4th 2020

The Honourable Patty Hajdu, P.C., M.P.
Minister of Health
Brooke Claxton Building, Tunney's Pasture Postal Locator: 0906C
Ottawa, ON K1A 0K9

Dear Minister Hajdu,

Subject: Federal price controls of patented medicines

On behalf of several of Canada's leading provincial life sciences organizations in Alberta, Ontario and Quebec, we are writing to bring to your attention new and concerning developments regarding the recent changes to the federal patented medicine price controls, including the August 2019 changes to the *Patented Medicine Regulations* and the draft Patented Medicine Prices Review Board (PMPRB) guidelines.

Over the past 2 years, hundreds of life sciences stakeholders – including patients, life sciences organizations, researchers and medicine developers across Canada – have registered their concerns regarding the serious impacts for the future of Canadian healthcare and our innovation economy, and that the proposed changes are in conflict with a number of stated goals of your government. These included serious impacts to economic investments and access to innovative, life-saving medicines for Canadians. Many of these concerns were highlighted in previous communications with your government and in formal consultations since 2017.

These concerns have now been validated. To help measure the impacts of the PMPRB changes, LSO engaged a third-party research firm to conduct an anonymous survey of Canadian and global life sciences leaders regarding how the PMPRB regulations will impact their operational, research, and commercialization plans in Canada. Over 45 respondents took part in the survey, ranging from Canadian-based biopharma companies who want to sell innovations in Canada and globally to large multinational firms with significant operations and research initiatives in Canada.

Specifically:

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- Nearly all respondents foresee no launch or delayed launch decisions for Canada (94%)
- Nearly all respondents believe there will be a decline in clinical trial activity and investment (91%)
- Nearly all respondents anticipate reduced employment in the life sciences sector (97%)
- Nearly three quarters indicated that the PMPRB changes will negatively impact patient support programs (73%) and reduce compassionate access programs (70%)
- The most impacted therapeutic areas will be in oncology, biologics, rare disorders, immunology, and gene/cell therapy – areas of the highest unmet medical need and where Canada currently excels globally in terms of science and research
- Some companies are already making these decisions in advance of the implementation date of the changes

In sum, we are no longer dealing with hypotheticals. We are dealing with people's lives, jobs, and the future of Canada's economic prosperity and competitiveness.

Across Canada, we are seeing the impact of the business uncertainty created by the PMPRB changes: jobs, research partnerships, and investments are all being lost. The health effects will inevitably follow as we start to experience diminished access to the latest innovative treatments.

While we understand and share the government's desire to pursue long-term sustainability of public healthcare; the approach being taken through PMPRB will not achieve this outcome. The supposed "cost savings" achieved by the new regulations are simply false economy. Real cost savings are achieved through collaborative processes like the (PCPA), where provinces ensure that all factors including supply of medicines are considered in decisions and ultimately, commitments by suppliers.

Many of us that are involved in life sciences policy are former public servants; we care about Canada's health system and understand the government's skepticism when presented with opposition to public policies from stakeholders. However, when it comes to health policy, what's at stake is the lives of Canadian patients. If you doubt the data above or the concerns raised by hundreds of submissions, we implore you to at least review the consequences of the federal price controls developed by a credible, unbiased research organization. This data reveals what's truly at stake for Canada's healthcare system and economy.

Ultimately, we need to assess the true value of innovative medicines and not just the sticker price. Research and innovation are key to addressing some of our greatest health challenges, including emerging global threats such as Ebola and the current spread of the coronavirus, in addition to growing health challenges at home, such as Alzheimer's, heart disease and cancer. By implementing the PMPRB changes in their current form, the Government of Canada is stifling global efforts to find curative therapies and vaccines. Let's not be short-sighted.

Our organizations strongly recommend that the Government of Canada reconsider the new price controls which are scheduled to come into effect on July 1, 2020 – for patients and the thousands of Canadians working to save and improve lives everywhere. Canadians deserve better.

Sincerely,



Jason Field
President & CEO
Life Sciences Ontario



Frank Béraud
Président-directeur général & CEO
Montréal InVivo



Robb Stoddard
President & CEO
BioAlberta



Carl Viel
President & CEO
Québec International



Encl.

- cc. The Right Honourable Justin P.J. Trudeau, P.C., M.P., Prime Minister of Canada
- The Honourable Bill Morneau, P.C., M.P., Minister of Finance
- The Honourable Navdeep Bains, P.C., M.P., Minister of Innovation, Science & Industry
- The Honourable Mélanie Joly, P.C., M.P., Minister for Economic Development & Official Languages
- The Honourable Mary Ng, P.C., M.P., Minister of Small Business, Export Promotion & International Trade
- Dr. Mitchell Levine, Chair of the Board, PMPRB