

Health Canada Pricing Reform

Research Report

January 21, 2021



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.

The regulatory changes include **revisions to the basket of comparator countries** (removing the US and Switzerland and adding six jurisdictions with lowerthan-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.

Three Key Research Objectives

- Measure familiarity with upcoming changes to price controls in Canada among Global and Canadian pharmaceutical decision-makers
- 2. Determine response (both actual and likely) to Canadian price control reforms, including any changes in product launch decisions and investments, including clinical trials, other research, employment, patient support programs, etc.
- 3. Confirm or refute the hypothesis that the new pricing regime will have no negative impacts on access to medicines and investments in Canada

NOTE: Research Etc. was commissioned to undertake a previous survey that was published in February 2020 and can be downloaded from Life Sciences Ontario's website; that project surveyed both pharmaceutical leaders *and* life sciences leaders and questions focused on anticipated impacts given that the PMPRB's operational plan for the regulations was not yet made public. The 2021 survey asked different questions, specifically, what are the anticipated and already undertaken changes in business plans.

Methodology



Based on N=43 completes

10-minute online survey with decisionmakers

Completes captured Dec 2 to Dec 15, 2020

Quantitative Sample Profile

N=43 Senior Pharmaceutical Executives (Presidents, GMs, EVPs, Director level)

- N=25 Canadian affiliate of a global company
- N=13 Parent company based outside Canada
- N=5 Parent company based in Canada



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

Fielded Dec 14 to Dec 18, 2020

Qualitative Deep Dive with ...

N=5 Larger Global pharma companies **N=5** Smaller companies, including Canadian-owned and headquartered



N=10 completes

PMPRB changes is the "#1 topic" among senior executives

In 2019, 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.

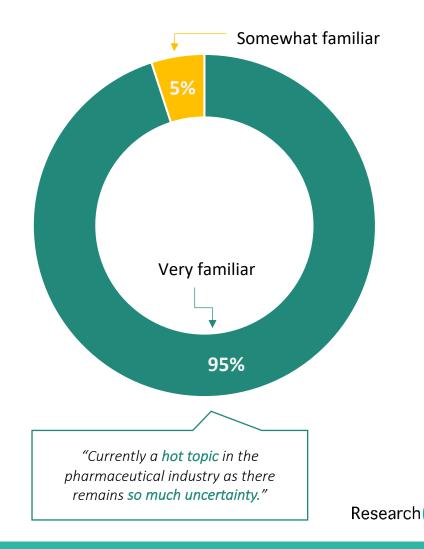
100%

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

95%

of pharmaceutical executives said they were "very familiar"

Q1. Overall, how familiar are you with the new PMPRB changes? (5-point scale: very familiar to not at all familiar) Base=43



Health Canada pricing exemption for COVID-19 vaccines/ therapeutics suggest policy weakness

Lessons from the pandemic: We need increased collaboration between the biopharmaceutical sector and government

"The reality is, had the government applied its new pricing guidelines to COVID-19 vaccine candidates, our ability to move at the speed of science would have been restricted. This should be a key learning.

As future innovative breakthrough treatments in areas such as oncology, rare disease and acute care are discovered, Canada needs to have a regulatory and pricing framework that encourages and fosters early access for patients."

Cole C. Pinnow, President of Pfizer Canada November 25, 2020 National Newswatch *"Imagine if COVID vaccines* are available in the US, UK and Europe but **not available in Canada** for a few years, if ever. That is the reality for any other drug but COVID, **it's a remarkable double standard**."

"Canadians would be furious if they couldn't get the COVID vaccine – it's an ill-thought-out malicious policy and a tacit acknowledgment on the part of government that they are wrong."

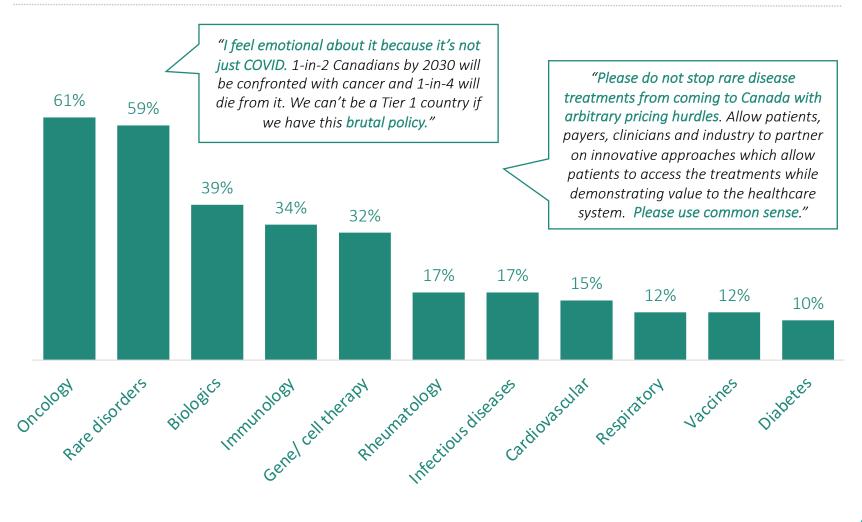
"How bad do your policies have to be to say that 'our policies won't apply to [COVID] life saving medicines'? PMPRB did that because [COVID affects] all Canadians – but how many oncology patients and rare disease patients will the rules apply to?"

"Proves if you need innovation, then the process inhibits it because they need to make Pfizer's innovation an exception."

Qualitative interviews (N=10): What is your reaction to Pfizer Canada receiving pricing exemption from the PMPRB to bring their COVID-19 vaccine to Canada?

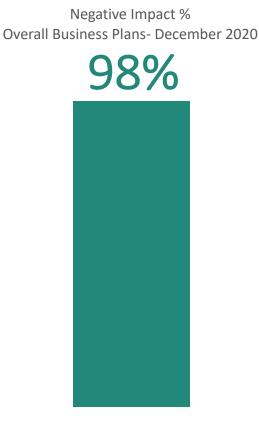
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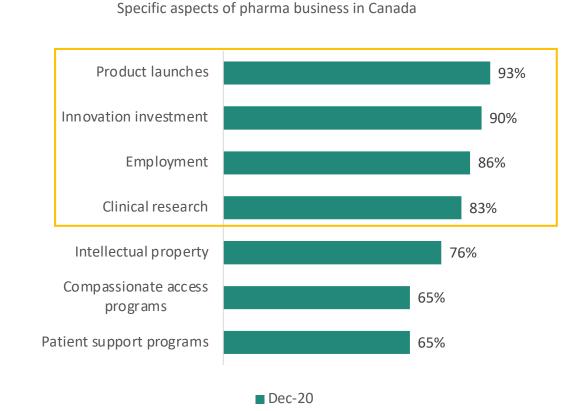
Pharma executives indicate that oncology, rare disease, chronic illnesses and even vaccines will be negatively impacted by pricing reforms





Virtually all pharma executives say new Health Canada pricing reforms is having a negative impact on their overall business plans in Canada



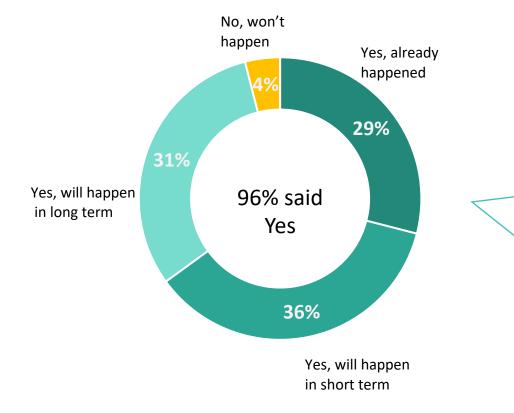


Negative Impact %

Q2. Please indicate the level of impact that the PMPRB changes will have or already have had on your plans in Canada by moving the slider scale to the position that best reflects your opinion for each of the following investments ? (5-point scale: significant positive impact to significant negative impact) Base=43 "N/A" excluded from the analysis

Researchetc.

Virtually all will make "no product launch" decisions in the short or long term – almost 30% have already made this decision



"We will be forced to withdraw a product from the market and will not proceed with the launch of another.

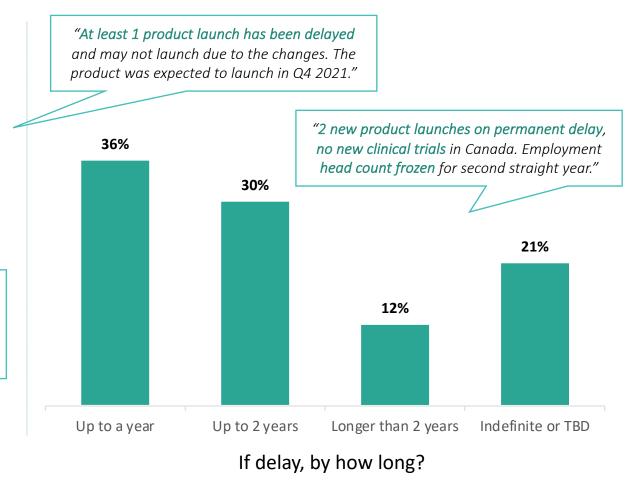
During our attempts to bring products to market both our parent company and potential partners feel that there is **too much pricing risk** to engage in the Canadian market and as such we are **not a priority country for launch or business development. Canadians will lag the world** in new product introductions."



Product launch delays are also a reality – over 1/3 say delays have already happened

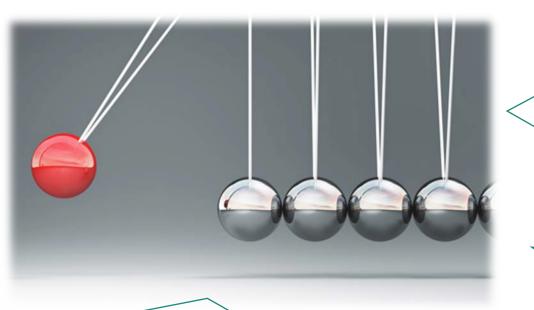
94% said Yes product launches will be delayed with **35%** saying it has already happened

"Launch timing of new products is being challenged in our organization. Decision to launch a new product for rare disease not yet decided due to uncertainty in the Canadian marketplace."



Research

90% say pricing reform will impact investments in research, clinical trials and innovation



"My job as CEO is to compete for a limited pool of funds my parent company has to bring opportunities to Canada, to attract investments here, to create jobs, run clinical trials, bring revenue here. I compete against the German division, the UK division, to get appropriate funding from Global head office. These policies make my job of attracting investments in Canada almost impossible." "As of now the company has not been generally impacted by it. However, we anticipate that there will be a **negative effect beginning in 2021 and beyond**. For example, we expect a delay in product launches ... This will make **Canada less attractive for clinical research and investment**, which will have an **impact on Canada's ability to attract talent and foster high-paying jobs**."

> "Be mindful this will have a further downstream effect on employment in this sector as well as innovation in Canada through clinical trials, etc."

"Investing in medicine *keeps people out of hospitals*. Stifling innovation is extremely shortsighted."

Q2. Please indicate the level of impact that the PMPRB changes will have or already have had on your plans in Canada? (5-point scale: significant positive impact to significant negative impact) Base=43 "N/A" excluded from the analysis; Q6. If you could only communicate one thing to the Canadian government about their intended PMPRB changes, what would it be; and from qualitative interviews



Virtually all say pricing reforms will impact direct and indirect employment – 1/3 say it's already happened

Impact on employment – cuts to current staff and future hiring plans

94% said Yes to deferred or cancelled staff hiring with **33%** saying it has already happened

"We've already experienced a **30% reduction in staff which means 160 people in total** – 30 hires in 2018 due to uncertainty and another 130 people in 2019. We now have a **hiring freeze**.

These are **educated, good paying jobs**, high taxable salaries in pharma sales jobs, medical, supporting jobs." "Our downsizing began in 2019 and has continued in 2020. Our current organizational footprint is 50% of what it was planned to be at this stage of our lifecycle."

"We would have been prepping for launch now so a half dozen jobs are lost directly, but also service providers: in scientific affairs, regulatory affairs, market access, market research and creative agencies."



Final message to the Canadian Government

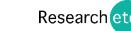
"This is not good for Canadians both short and long term and will severely and negatively impact the health and well being of Canadians. We are not an attractive market and decisions are being made to invest elsewhere and not bring products to market. Further, employment and the entire network of economic contribution will be lost when we need to rebuild the economy."

"The government does not truly recognize the contribution as innovators we create and the number of Canadians we employ, or the investments made to ensure patients have access through patient support or compassionate programs. We need to work in partnership not in isolation and not solely on the basis of cost."

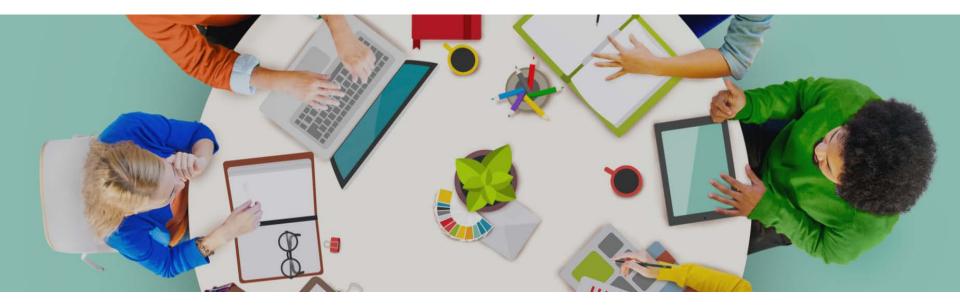


"The changes as proposed are already impacting patient accessibility to new innovative therapies that other G7 nations have much more predictable and favorable access to, they are already impacting employment, and overall market attractiveness of Canada as a destination for pharma.

What is most concerning is that this is clearly understood by people in political and bureaucratic circles and is best evidenced by divergent COVID-related decisions. COVID has taught us that access to innovation is important."



Q6. If you could only communicate one thing to the Canadian government about their intended PMPRB changes, what would it be? (N=43)



Thank you!

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