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 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.

Three Key Research Objectives

1. **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

**STEP 1: Quantitative research**

Based on N=43 completes
10-minute online survey with decision-makers
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

**STEP 2: Qualitative research**

N=10 completes
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
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

“Currently a hot topic in the pharmaceutical industry as there remains so much uncertainty.”
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?
Pharma executives indicate that oncology, rare disease, chronic illnesses and even vaccines will be negatively impacted by pricing reforms

Q5. Which of your therapeutic areas in Canada, if any, are likely to be impacted as a result of the new PMPRB changes? Base=43

“Please do not stop rare disease treatments from coming to Canada with arbitrary pricing hurdles. Allow patients, payers, clinicians and industry to partner on innovative approaches which allow patients to access the treatments while demonstrating value to the healthcare system. Please use common sense.”

“I feel emotional about it because it’s not just COVID. 1-in-2 Canadians by 2030 will be confronted with cancer and 1-in-4 will die from it. We can’t be a Tier 1 country if we have this brutal policy.”

Q5. Which of your therapeutic areas in Canada, if any, are likely to be impacted as a result of the new PMPRB changes? Base=43
Virtually all pharma executives say new Health Canada pricing reforms is having a negative impact on their overall business plans in Canada.

98% Overall Business Plans - December 2020

<table>
<thead>
<tr>
<th>Specific aspects of pharma business in Canada</th>
<th>Negative Impact %</th>
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<tbody>
<tr>
<td>Product launches</td>
<td>93%</td>
</tr>
<tr>
<td>Innovation investment</td>
<td>90%</td>
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<tr>
<td>Employment</td>
<td>86%</td>
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<tr>
<td>Clinical research</td>
<td>83%</td>
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<tr>
<td>Intellectual property</td>
<td>76%</td>
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<tr>
<td>Compassionate access programs</td>
<td>65%</td>
</tr>
<tr>
<td>Patient support programs</td>
<td>65%</td>
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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.
Virtually all will make “no product launch” decisions in the short or long term – almost 30% have already made this decision.

96% said Yes

- Yes, will happen in long term: 31%
- Yes, already happened: 4%
- Yes, will happen in short term: 36%
- No, won’t happen: 29%

“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.”

Q5. Do you foresee or have you already experienced “no launch decisions for medicines in Canada” due to pricing reforms? (Base=43)
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

“At least 1 product launch has been delayed and may not launch due to the changes. The product was expected to launch in Q4 2021.”

“If delay, by how long?

- Up to a year: 36%
- Up to 2 years: 30%
- Longer than 2 years: 12%
- Indefinite or TBD: 21%

“2 new product launches on permanent delay, no new clinical trials in Canada. Employment head count frozen for second straight year.”

“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.”

Q5. Do you foresee or have you already experienced “delayed launches for medicines in Canada” due to pricing reforms? If yes, by how long? (Base=43)
90% say pricing reform will impact investments in research, clinical trials and innovation

“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.”

“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.”

“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

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.”

Q5. Do you foresee or have you already experienced “Deferring or canceling hiring staff” due to pricing reforms? (Base=43)
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!

Rachelle Deshaies | rachelle@researchetc.com | 1.416.845.8565