EARLY SIGNS OF NEGATIVE IMPACTS FOR PATIENTS OF HEALTH CANADA PHARMACEUTICAL PRICING REFORMS

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INTRODUCTION

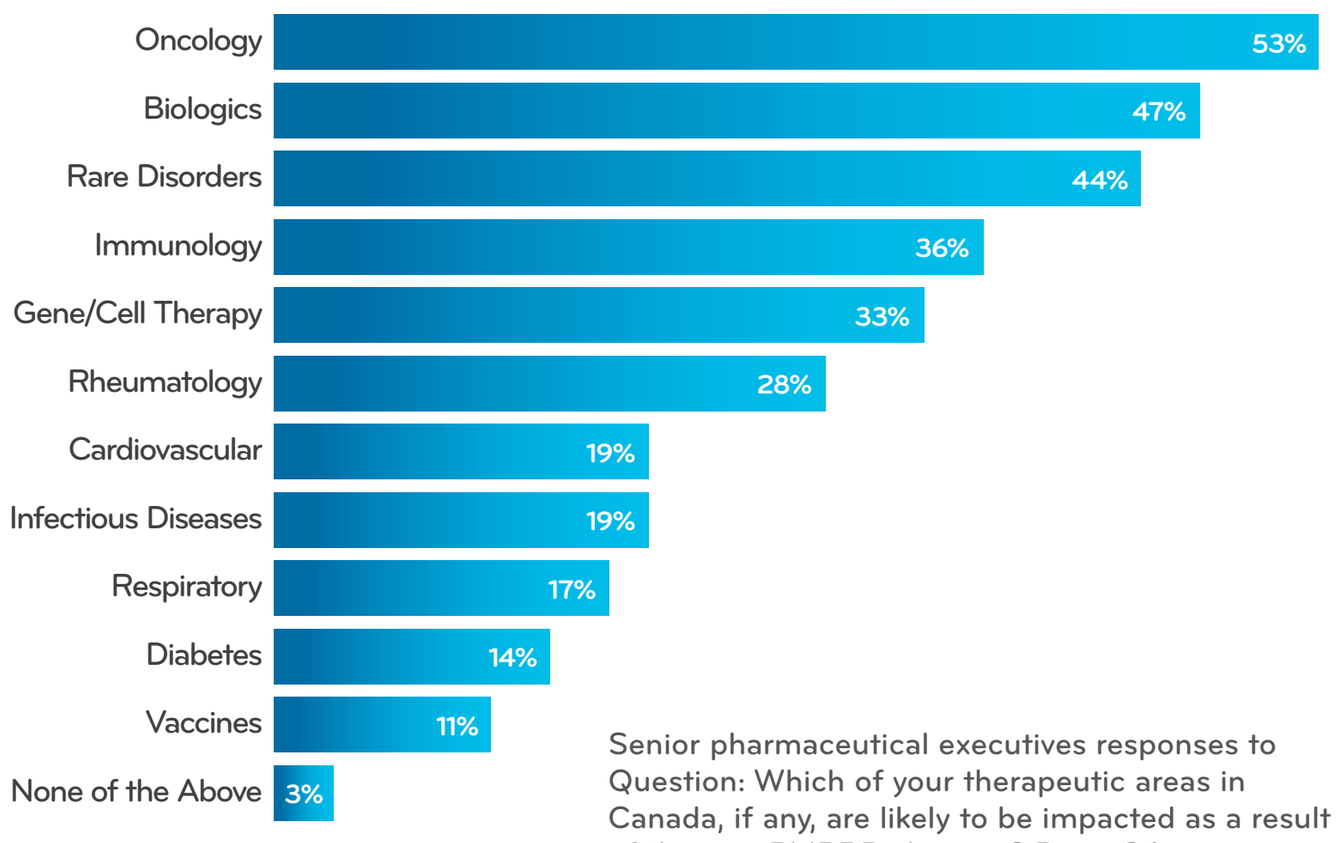
The Patented Medicine Prices Review Board recently proposed a sweeping and controversial reform of its 30-year old regime overseeing patented medicine prices. The potential negative impact of this reform on the life sciences sector and patients' access to medicines has been dismissed despite early evidence to the contrary[1]. The Regulations were published in Canada Gazette[2] (CG2) in August 2019, and early signs of its negative impact are already becoming apparent.

METHODS

Combining data from an opinion survey of pharmaceutical manufacturers with objective metrics on clinical trials, new drug submissions and launches obtained from publicly-available government and commercial databases such as Informa Citeline, Health Canada's NOC, Drug Product and Drug and Health Product Submissions Under Review databases, and EMA and FDA databases, these metrics following the publication of CG2 are compared to historical trends.

① CHANGES TO THE PMPRB ARE KEEPING POTENTIALLY LIFE-CHANGING MEDICINES OUT OF CANADIANS' HANDS.[3]

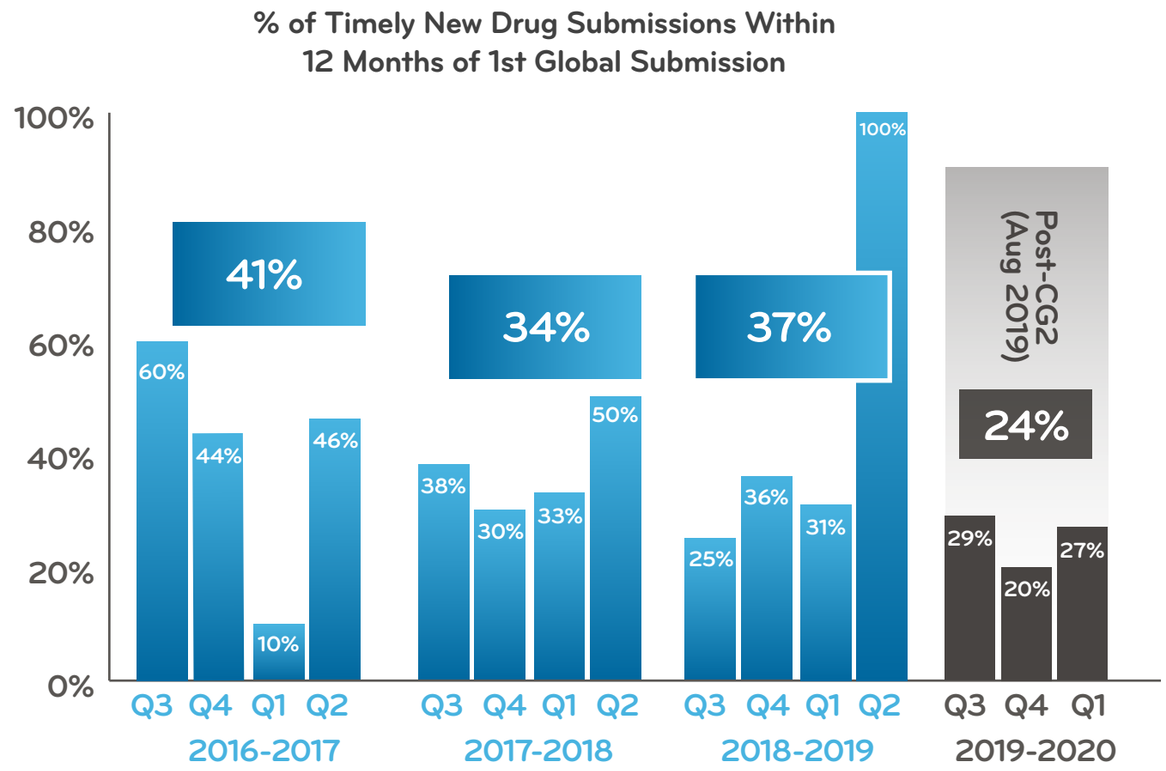
Therapeutic areas likely to be impacted

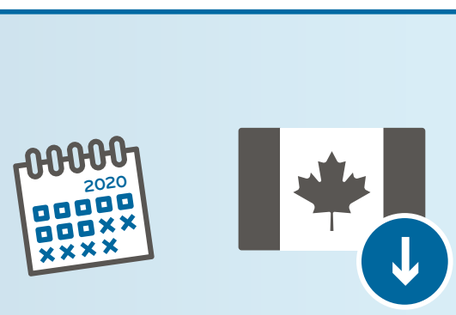


Senior pharmaceutical executives responses to Question: Which of your therapeutic areas in Canada, if any, are likely to be impacted as a result of the new PMPRB changes? Base=36

> "The Canadian government and particularly Health Canada have completely forgotten about the people it should be serving and helping: Canadian patients. There will be delayed access or, worse, no access to new medicines as a result of these changes, and this will harm patients."
>
> -CANADIAN ORGANIZATION FOR RARE DISORDERS

② SINCE THE REGULATIONS WERE PASSED, THERE HAVE BEEN FEWER TIMELY NEW DRUG SUBMISSIONS FOR HEALTH CANADA APPROVAL[4]





In the 9 months following CG2, there was a **decline in timely submissions made in Canada to 24% of global submissions, compared to 35-40% in the 3 previous 12-month periods.**

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③ THERE HAS BEEN AN INCREASE IN DELAYED DRUG LAUNCHES SINCE THE REGULATIONS WERE PASSED[5]

In the 9 months following CG2, delayed or cancelled launches doubled to **42% of approvals, compared to the 3 previous 12-months.**

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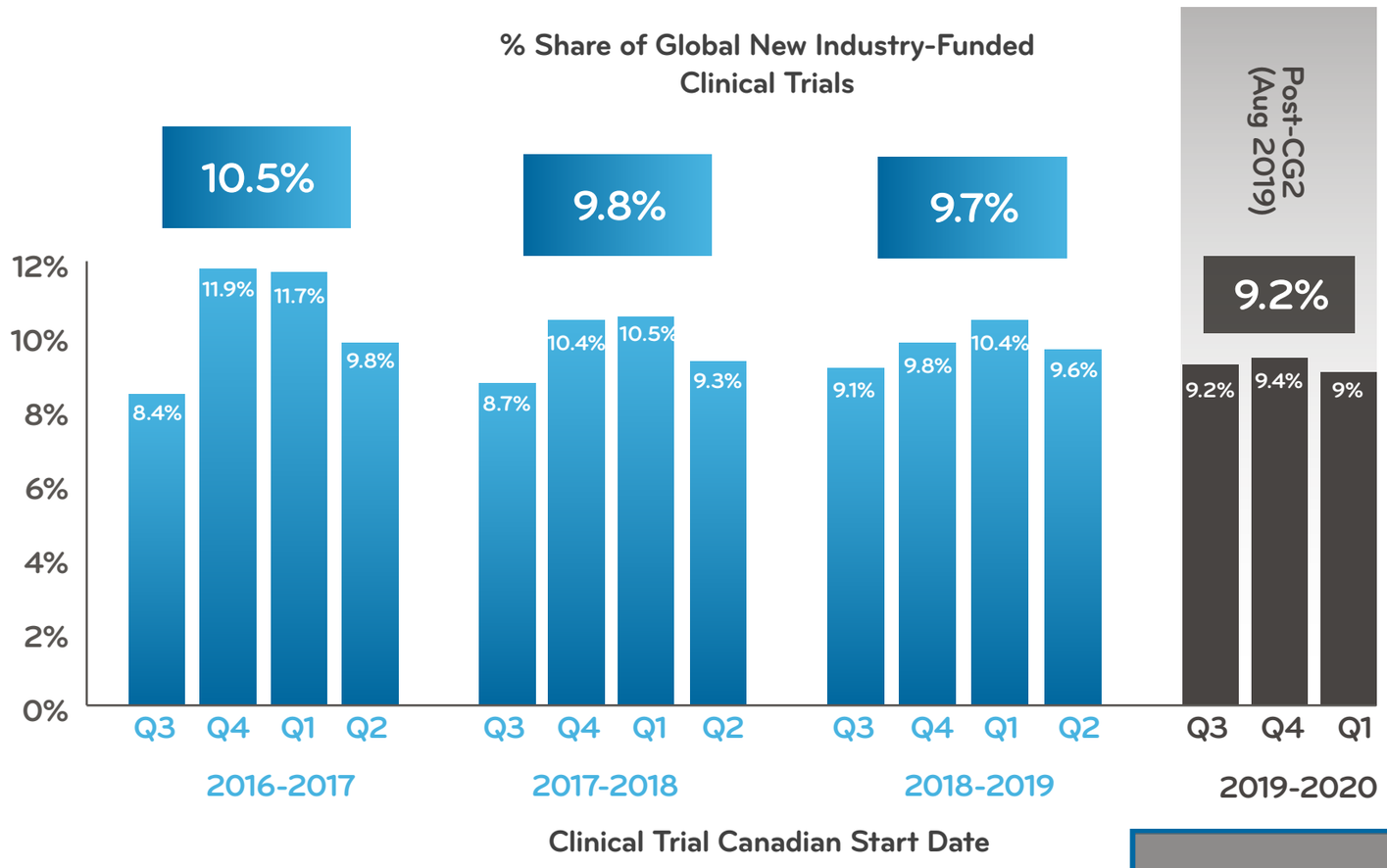
4 SINCE THE NEW REGULATIONS WERE PASSED, PRELIMINARY DATA SUGGESTS CANADA MAY BE EXPERIENCING A DECREASE IN INDUSTRY-FUNDED DRUG CLINICAL TRIALS[6]

As of early June 2020, Informa data suggest that there was a decline in the share of global industry-funded clinical trials that were started in Canada in the 9 months following CG2 to 9% compared to around 10% in the 3 previous 12-month periods.



Clinical trials are a critical step towards bringing new medicines and vaccines safely to market, and provide Canadians with access to new, potentially lifesaving medications and therapies.

5 PATIENTS REMAIN OPPOSED TO THE PMPRB CHANGES AND ARE JUSTIFIABLY CONCERNED THAT IMPLEMENTATION WILL DELAY AND EVEN PREVENT NEW MEDICINES FROM COMING TO CANADA.[3]

"The federal government made it clear they either don't understand–or they don't care–about the devastating impact of the new drug pricing regulations on the 1 in 12 Canadians with rare disease –two-thirds of them children–or any patient waiting for a life-saving new therapy."

-John Adams, Best Medicines Coalition, representing more than 30 patient organizations

"If this pricing scheme had been in place five years ago when the first drug for CF was available, I would probably not be alive today."

-Chris MacLeod, CF Treatment Society

"I was worried when I heard about (the PMPRB) regulations, now I have heard more, I am scared... scared for my patients."

-Lanre Tunji-Ajayi, Sickle Cell Disease Association of Canada

CONCLUSIONS

Although many factors can explain business investment decisions, these signals of negative trend coincide with the release of CG2. This indicates that companies may already be making decisions due to business uncertainty that are having a negative impact on patient access to new medicines which could potentially be attributed to CG2.

More time is needed to fully assess the impact of these potential changes, and further consultations are needed to find a balanced policy approach.

REFERENCES AND NOTES

[1] Ernst and Young. An Assessment of Canada's Current and Potential Future Attractiveness as a Launch Destination for Innovative Medicines. Innovative Medicines Canada. January 2019; and Skinner, Brett J. Patented drug prices and clinical trials in 31 OECD countries 2017: implications for Canada's PMPRB. Canadian Health Policy, August 2019. Canadian Health Policy Institute (CHPI).

[2] Government of Canada, Canada Gazette Part 2, Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298.

[3] Research etc. Impact of PMPRB Pricing changes, final Research Report. Life Sciences Ontario, February 3, 2020.

[4] Health Canada, NOC database and Submissions Under Review database, EMA and FDA websites. Submission delay is the difference between date of first global submission and Health Canada submission date. Analysis by Innovative Medicines Canada, with feedback from the Conference Board of Canada.

[5] Health Canada, NOC database and Drug Product database. Launch delay is the difference between date of Health Canada approval and first marketed date. Analysis by Innovative Medicines Canada, with feedback from the Conference Board of Canada.

[6] Informa Pharma Intelligence, Citeline. Data as of June 10, 2020. Analysis by Innovative Medicines Canada, with feedback from the Conference Board of Canada. Note: There is a lag in data reporting and as a result the data for the last 6 months especially is likely under-reported, however, only time will tell by how much.