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 contrary1. The Regulations were published in Canada Gazette² (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

2 SINCE THE REGULATIONS WERE PASSED, THERE HAVE BEEN FEWER TIMELY NEW DRUG SUBMISSIONS FOR HEALTH CANADA APPROVAL³

3 THERE HAS BEEN AN INCREASE IN DELAYED DRUG LAUNCHES SINCE THE REGULATIONS WERE PASSED³
SINCE THE NEW REGULATIONS WERE PASSED, PRELIMINARY DATA SUGGESTS CANADA MAY BE EXPERIENCING A DECREASE IN INDUSTRY-FUNDED DRUG CLINICAL TRIALS

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.

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

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.

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