

# Merck Canada Inc.

Submission to the House of Commons Standing Committee on Finance (FINA)

Priorities for the 2022 Federal Budget

August 6, 2021



# **Summary of Recommendations**

## Recommendation #1

That the government halt the current pharmaceutical pricing reforms and conduct a review of the Patented Medicine Prices Review Board to ensure federal price reviews and controls do not create barriers to access to medicines and vaccines in Canada and undermine the federal government's Biopharmaceutical and Life Sciences Strategy goal of growing the sector to build Canada's resiliency in the face of pandemics and other health challenges.

## **Recommendation #2**

That the government invest in new COVID-19 antiviral medicines as part of its preparedness plan to protect Canadians against the current and future pandemics and ultimately ensure their health and economic security.

## **Recommendation #3**

That the government **increase the Canada Health Transfer** to the provinces/territories to allow them to invest more in cancer care and treatments to facilitate a return to care from the COVID-19 pandemic and meet the growing health needs due to the aging population.

#### **Recommendation #4**

That the government provide additional funding to allow provinces/territories to catch up with school-based vaccination programs – including vaccines for human papillomavirus (HPV) infection – that were disrupted due to the COVID-19 pandemic to prevent illnesses, limit healthcare costs and promote better population health.



# **Merck Canada Background**

For over a century, Merck Canada (Merck) has been inventing for life, developing medicines and vaccines for many of the world's most challenging diseases. Merck is a global biopharmaceutical company with a diversified portfolio of prescription medicines, vaccines and biologic therapies, including biosimilars.

In Canada, Merck is a leader in many areas such as oncology, vaccines, hospital acute care, infectious diseases and diabetes, and markets more than 250 pharmaceutical and animal health products. Merck employs approximately 630 people across the country.

Merck is also one of the top R&D investors in Canada, with investments totalling more than \$1 billion since 2000. Merck is committed to supporting Canada as a destination for research, investment and clinical trials – activities that promote Canada's economy and international competitiveness. Merck is currently investing in over 100 clinical trials involving 500+ research sites and 3,000+ patients across Canada.

Merck has also responded to the COVID-19 pandemic by committing \$500,000 to its COVID-19 Community Support Plan in Canada and is currently developing an antiviral treatment for COVID-19.

# **Rationale for Recommendations**

# **Recommendation #1**

That the government halt the current pharmaceutical pricing reforms and conduct a review of the Patented Medicine Prices Review Board to ensure federal price reviews and controls do not create barriers to access to medicines and vaccines in Canada and undermine the federal government's Biopharmaceutical and Life Sciences Strategy goal of growing the sector to build Canada's resiliency in the face of pandemics and other health challenges.

The life sciences sector of the Canadian economy is crucial not just for its contributions to economic activity in Canada – though these are substantial – but also in helping protect Canadians from serious health challenges such as COVID-19 as well as other diseases and conditions.

The regulatory amendments first announced in 2017 and published by the federal government in August 2019 will change how the Patented Medicine Prices Review Board (PMPRB) regulates the prices of patented medicines. These price controls are untested and unprecedented in any jurisdiction and will introduce a complex and bureaucratic regime. Canada will lose its status as an early market for new medicines<sup>1</sup> and as a prime location for global clinical studies,<sup>2</sup> which will have a detrimental effect on the health of all Canadians.

<sup>&</sup>lt;sup>1</sup> <a href="https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN\_LSO\_Global-Launch-Benchmarking\_Webinar-June22-20">https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN\_LSO\_Global-Launch-Benchmarking\_Webinar-June22-20</a> Final.pdf

<sup>&</sup>lt;sup>2</sup> <a href="https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-remain-despite-pmprb---s-superficial-response.html">https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-remain-despite-pmprb---s-superficial-response.html</a>



This policy runs counter to one of the key goals of Canada's Biomanufacturing and Life Sciences Strategy which is to grow a strong, competitive life sciences sector, and one of the strategy's five pillars, "Enabling Innovation by Ensuring World Class Regulation" in order to "make Canada a more attractive destination for leading life sciences firms to establish and grow."<sup>3</sup>

FINA itself in February 2021 recommended to the government that it, "Ensure that the Patented Medicine Prices Review Board changes do not create barriers for new medicines for Canadians."<sup>4</sup>

While the government has delayed the implementation of the new pricing regulations three times in order to permit the industry to focus on alleviating the COVID-19 pandemic, the PMPRB has pushed forward during these delays with new iterations of its Guidelines to implement them. Most recently, on July 16, 2021 – just days after the government announced the latest regulation implementation delay – the PMPRB introduced unexpected new provisions to further control and decrease the prices of already marketed medicines in Canada.

These actions by this PMPRB clearly run counter to the stated policy of the government and of Parliament as voiced by FINA, as they will strain already challenged drug supply chains. In addition, a recent Federal Court of Appeal found that the PMPRB is acting outside the scope of its mandate, arguing that it has a "consumer protection mandate" under the *Patent Act*, which it does not. In reviewing the PMPRB's statements on the price of a medicine, the Court noted: "Statements like these, unless explained against the statutory standard, smack as price control, not policing for excessiveness."<sup>5</sup>

As the PMPRB is accountable directly to Parliament, FINA is an appropriate authority to call for a review of the actions and leadership of the PMPRB to ensure it is acting according to its legislated mandate under the *Patent Act* and as an impartial regulator of industry and not, as seems apparent, as the country's developer of drug price controls policy. We urge FINA to strongly consider launching this vital oversight action.

We also strongly encourage the government to halt the current PMPRB pricing reforms and conduct a constructive dialogue on the issue with industry and other stakeholders to meet the objectives of the government's Biomanufacturing and Life Sciences Strategy.

## **Recommendation #2**

That the government invest in new COVID-19 antiviral medicines as part of its preparedness plan to protect Canadians against the current and future pandemics and ultimately ensure their health and economic security.

While vaccines are certainly helping limit the spread and seriousness of cases of COVID-19, it is becoming clear they will likely not eliminate the virus. Canada must be prepared to continue to fight COVID-19 on many fronts for many years. The government has recognized this with one of the

<sup>&</sup>lt;sup>3</sup> https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html

<sup>&</sup>lt;sup>4</sup> https://www.ourcommons.ca/DocumentViewer/en/43-2/FINA/report-1/page-21

<sup>&</sup>lt;sup>5</sup> Alexion v. Canada 2021 FCA https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do



objectives of its new Biomanufacturing and Life Sciences Strategy being "to make sure Canada is prepared for pandemics and other health emergencies in the future."

An important aspect of achieving this objective is for the government to continue to secure advance purchases of new COVID-19 and other antiviral medicines that are being developed to secure supply of these important treatments to help Canadians deal with the ongoing pandemic and other potential outbreaks.

## **Recommendation #3**

That the government increase the Canada Health Transfer to the provinces/territories to allow them to invest more in cancer care and treatments to facilitate a return to care from the COVID-19 pandemic and meet the growing health needs due to the aging population.

Even before the COVID-19 pandemic, Canada's health systems were under immense strain to meet the needs of our aging population and the associated increasing incidence of cancer. Older Canadians are more at risk of cancer, given that 90% diagnosed with cancer are aged 50 years and older. The Canadian Cancer Society is forecasting a 40% increase in cancer incidence between 2015 and 2030.

Now, health systems have been severely impacted by the pandemic, creating large backlogs for many types of interventions and treatments, including in critical areas such as cancer care. Dr. Jonathan Irish, head of surgical oncology at Cancer Care Ontario and Ontario Health, has said that the health system faces a "tsunami" of patients whose diagnosis and treatment was delayed and now have more advanced disease, adding that "the collateral damage of COVID-19 in many areas is going to be significant."<sup>8</sup>

The federal government is positioned to lead by helping the provinces meet these huge challenges through increased Canada Health Transfer (CHT) and by calling out the need to prioritize cancer care as part of our country's post-COVID recovery plan.

In particular, Merck supports the call of the provinces for the federal government to increase the CHT to 35% of provincial health costs from the current 22%. This will help provinces address the growing health demands, including providing timely access to cancer treatments such as immunotherapies. These new treatments, which harness the body's own immune system to fight and kill the cancer cells, have become the fourth pillar of cancer care alongside surgery, radiotherapy and chemotherapy.

It is encouraging that the Prime Minister has committed to increasing the CHT once Canada is "through the worst" of the pandemic. 10 We strongly encourage the government to implement this commitment in Budget 2022.

<sup>&</sup>lt;sup>6</sup> http://www.cancer.ca/~/media/cancer.ca/CW/publications/Canadian%20Cancer%20Statistics/Canadian-Cancer-Statistics-2019-EN.pdf

 $<sup>^{7}\,\</sup>underline{\text{http://www.cancer.ca/en/about-us/for-media/media-releases/national/2015/canadian-cancer-statistics-2015/?region=on}$ 

<sup>8</sup> http://cmajnews.com/2021/05/17/covid-cancer-1095944/

<sup>9</sup> https://www.canadaspremiers.ca/wp-content/uploads/2021/03/COF\_NR\_CHT-final.pdf

<sup>&</sup>lt;sup>10</sup> https://www.theglobeandmail.com/politics/article-ottawa-will-increase-health-transfers-to-the-provinces-after-the/



# **Recommendation #4**

That the government provide additional funding to allow provinces/territories to catch up with school-based vaccination programs – including vaccines for human papillomavirus (HPV) infection – that were disrupted due to the COVID-19 pandemic to prevent illnesses, limit healthcare costs and promote better population health.

The COVID-19 pandemic has demonstrated even more clearly the value of vaccines in preventing the toll and expense of illness, including cancer.

In 2007, the federal government invested \$300 million to support HPV immunization programs that have prevented a significant number of future HPV-related cancers and diseases and associated costs. This vaccination program is delivered by the provinces/territories at schools. The COVID-19 interruptions of in-person learning, however, have also disrupted this vital immunization program to a whole academic year of young Canadians, if not more.

The federal government should provide additional funding that will allow the provinces/territories to initiate a catch-up program to reach, educate and vaccinate those young Canadians who have missed their HPV immunization during the last school year to ensure this program continues to benefit all eligible Canadians. This will also help Canada achieve its international commitment of reaching a 90% uptake of this vaccine among Canadians aged 9 to 26,<sup>11</sup> compared to the prepandemic national rate of only 67%.<sup>12</sup>

<sup>11</sup> https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html

<sup>&</sup>lt;sup>12</sup>https://content.cancerview.ca/download/cv/quality\_and\_planning/system\_performance/documents/2018 cancer\_system\_performance\_report\_enpdf?attachment=0&utm\_source=Landing Page&utm\_medium=Full Report&utm\_campaign=Omnibus