

**Submission for the Pre-Budget Consultations in
Advance of the 2019 Budget**

By Merck Canada Inc.

Summary of Recommendations

Recommendation #1

That the federal government increase the Canada Health Transfer (CHT) to at least 5.2% annually to allow provinces/territories to meet the increasing health needs resulting from the aging of the population and corresponding rising incidence of cancer, including providing timely access to cancer immunotherapies.

Recommendation #2

That the federal government commit \$100 million annually for a public vaccine funding mechanism to help provinces/territories invest in vaccine adoption – including vaccines for human papillomavirus (HPV) infection for both males and females – and vaccine education programs.

Recommendation #3

That the federal government revise the proposed amendments to the *Patented Medicines Regulations* to ensure a balanced approach supporting Canada's competitiveness in global biopharmaceutical and medical research and timely access by Canadians to innovative medicines.

Recommendation #4

That the federal government develop a national pharmacare program that provides Canadians with universal, timely and high-quality access to medicines within a sustainable health system that maintains public and private drug insurance coverage.

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 leading global biopharmaceutical company with a diversified portfolio of prescription medicines, vaccines, biologic therapies including biosimilars and animal health products. In Canada, Merck is a leader in a broad range of areas such as oncology, infectious diseases, diabetes and vaccines, and markets more than 250 pharmaceutical and animal health products. Headquartered in Quebec, Merck employs nearly 800 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 115 clinical trials involving over 450 research sites and 1,800 patients across Canada.

In this submission, Merck makes four recommendations that will help drive Canada's economic growth and competitiveness by:

- Ensuring that the Canadian workforce is healthier and more productive.
- Improving the health of all Canadians, our health system and our knowledge-based economy.

Background and Rationale for Recommendations

Recommendation #1

That the federal government increase the Canada Health Transfer (CHT) to at least 5.2% annually to allow provinces/territories to meet the increasing health needs resulting from the aging of the population and corresponding rising incidence of cancer, including providing timely access to cancer immunotherapies.

Provincial/territorial health systems across Canada face huge, immediate and near-future challenges to meet the increasing demands due to the aging of the population and the associated increasing incidence of cancer, among other drivers.

Statistics Canada predicts that by 2036 there will be 9.9-10.9 million Canadians age 65 or older¹ compared with 6.2 million in 2017² – an increase of 60% to 75%. These citizens will be living longer and with more chronic diseases. The federal government has recognized the importance of this demographic shift by reinstating a Minister of Seniors in July 2018.

Cancer is placing increasing demands on our health system. The Canadian Cancer Society states that one of every two Canadians can expect to have cancer during their life. By 2030, the number of cancers diagnosed is projected to be almost 80% greater than the number diagnosed

¹ Statistics Canada, Population projections for Canada, Highlights: <http://www.statcan.gc.ca/pub/91-520-x/2010001/aftertoc-aprestdm1-eng.htm>.

² Statistics Canada, Population by sex and age group, 2017: <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo10a-eng.htm>.

in 2005. At the same time, more new and promising treatments will become available, contributing further to the declines in cancer death rates we have already seen: 32% for males and 16% for females between 1988 and 2017.³

Canadians are concerned about the ability of health systems to keep up with the demand. A poll conducted by Ipsos Canada for the Canadian Medical Association (CMA) released in July 2018 showed that just half of Canadians have confidence that the health system will be able to meet the growing needs of seniors who are disproportionately impacted by cancer.⁴

Merck supports the call by the CMA to address these challenges by having the federal government significantly increase the CHT to the provinces/territories. A recent analysis conducted by the Conference Board of Canada for the CMA shows that over the next decade an additional \$93 billion in health care spending will be needed – an amount the report says is equivalent to almost 2% of *total* provincial/territorial spending.⁵ Earlier Conference Board of Canada estimates indicate that healthcare inflation is rising at 5.2% annually, well over the current CHT rate of 3%.⁶

In cancer, important new treatments include immunotherapies that harness the body's own immune system to fight and kill the cancer cells. Merck's new immunotherapy and others have already been shown to be effective in a number of different cancers (e.g. metastatic melanoma, non-small cell lung cancer, refractory or relapsed classical Hodgkin lymphoma and bladder cancer) and studies are under way in numerous other cancers. As Canadians learn more about how immunotherapies are fast becoming the standard of care in oncology, the demand for these treatments will increase. The federal government can enable provinces/territories to provide these life-saving therapies to Canadians by increasing the CHT.

Recommendation #2

That the federal government commit \$100 million annually for a public vaccine funding mechanism to help provinces/territories invest in vaccine adoption – including vaccines for human papillomavirus (HPV) infection for both males and females – and vaccine education programs.

Vaccines are effective tools to prevent diseases, reduce healthcare costs and alleviate suffering. They offer economic benefits through reduced work absences, hospitalization and decreased demand for other expensive treatments, including visits to emergency rooms and physicians.

³ Canadian Cancer Society, *Canadian Cancer Statistics: A 2018 Special Report*, p. 6: <http://www.cancer.ca/~media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2018-EN.pdf?la=en>.

⁴ Ipsos Canada, July 17, 2018, <https://www.ipsos.com/en-ca/news-polls/Canadian-Medical-Association-Seniors-July-17-2018>.

⁵ Canadian Medical Association, CMA to premiers: Federal funding needed to meet seniors' care needs, July 2018, <https://www.cma.ca/En/Pages/CMA-to-premiers-Federal-funding-needed-to-meet-seniors%E2%80%99-care-needs-.aspx>.

⁶ Analysis completed for provincial and territorial governments and referenced in the Quebec Provincial Budget, 2017-18, among other sources, http://www.budget.finances.gouv.qc.ca/budget/2017-2018/en/documents/Budget1718_Health.pdf.

For instance, prophylactic vaccines are the most effective way to prevent HPV infection and HPV-related diseases, as there is currently no cure for an HPV infection. Seven HPV types are responsible for 90% of invasive cervical cancers in the world. Infection with high-risk HPV types is also linked to several other cancers.⁷

In 2007, the federal government invested \$300 million to support HPV immunization programs for over 1.7 million girls across Canada. As a result, all provinces and territories funded HPV vaccination programs and the number of HPV-related diseases prevented as a result of the program has been significant. As evidence emerged on the health benefits to males, provinces/territories have since expanded HPV immunization programs to include males.

However, more needs to be done to ensure increased uptake of HPV and other vaccines in Canada. The recommended funding would help provinces/territories continue to implement HPV and other immunization programs. Part of this funding could also be applied to communication and education activities to ensure more Canadians are aware of the opportunity to access vaccines across Canada. This would help the federal government meet its global commitment to achieve the target of 90% of HPV immunization uptake by 2030.⁸

Ultimately, this funding mechanism would help ensure that the Canadian workforce is healthier and increase Canada's competitiveness.

Recommendation #3

That the federal government revise the proposed amendments to the *Patented Medicines Regulations* to ensure a balanced approach supporting Canada's competitiveness in global biopharmaceutical and medical research and timely access by Canadians to innovative medicines.

Proposed amendments to the *Patented Medicines Regulations*, which will change the way in which the Patented Medicine Prices Review Board (PMPRB) assesses patented drug prices, will have serious negative consequences on Canada's economic competitiveness in the medical and biopharmaceutical research field and patient access to innovative medicines.

- These amendments will reduce research investments and health innovation partnerships and lead to the loss of quality jobs in the pharmaceutical and related sectors in Canada. Investment decisions in clinical research are long-term, and global operations look to invest in jurisdictions that have a strong, predictable and business-friendly environment. The proposed amendments are sending the wrong signals for global investments.

⁷ Federation of Medical Women of Canada – HPV Prevention Week Press Release
<https://fmwc.ca/hpvprevention-week-press-release>.

⁸ Reducing the health impact of sexually transmitted and blood-borne infections in Canada by 2030: A pan-Canadian STBBI framework for action, July 2018:
<https://www.canada.ca/content/dam/phac-aspc/documents/services/infectious-diseases/sexual-health-sexually-transmitted-infections/reports-publications/sexually-transmitted-blood-borne-infections-action-framework/sexually-transmitted-blood-borne-infections-action-framework.pdf>.

- Canada has benefitted to date from “Tier 1” status, meaning that Canadians are among the first in the world to access to new medicines. However, the proposed amendments will jeopardize this status because profound drug price reductions combined with a complex and uncertain regulatory process will lead to launch delays or decisions not to launch some medicines in Canada.

Merck is concerned that the proposed reform, especially the introduction of new economic criteria, is untested and unprecedented in any other jurisdiction and will lead to an unworkable price control system. The government needs to reconsider these amendments given its latest regulatory modernization consultation, which seeks to “explore ways to enable regulations to be more agile, transparent, and responsive so that Canadian businesses can grow, resulting in benefits for all Canadians.”⁹

The proposed changes run counter to Canada’s Innovation and Skills Strategy and are also likely contrary to some of Canada’s international treaty and trade commitments. This would be detrimental to creating a positive climate for international investment, which is crucial to building Canada’s economic competitiveness.

Merck strongly recommends the government postpone the implementation of these amendments in favour of a more balanced and workable approach developed with the pharmaceutical industry and other stakeholders. There is a way of ensuring reasonable drug prices while maintaining a strong health research ecosystem in Canada. A balanced approach would also benefit Canadians by providing them with early access to innovative medicines through clinical trials and early launches of new medicines in Canada.

Recommendation #4

That the federal government develop a national pharmacare program that provides Canadians with universal, timely and high-quality access to medicines within a sustainable health system that maintains public and private drug insurance coverage.

Merck agrees with the need to address gaps in access to medicines by developing a national pharmacare program. Done right, this program would contribute to increasing Canada’s economic productivity and competitiveness.

Merck believes a national pharmacare program should be based on five key principles:

- **Universal coverage:** Ensure all Canadians have access to the medicines they need when they need them, no matter where they live, how much they make or how old they are so all Canadians can benefit from appropriately prescribed and administered treatments.
- **Timely coverage:** Ensure that reviews and reimbursement decisions for medicines are made in a reasonable timeframe so patients aren’t kept waiting for treatments they need.
- **High-quality coverage:** Canadians should have access to a range of therapeutic options to ensure the treatment that is right for them is available to them.

⁹ Regulatory modernization: <http://gazette.gc.ca/rp-pr/p1/2018/2018-07-28/html/notice-avis-eng.html#n17>.

- **Sustainable health system:** All involved are responsible for ensuring a national pharmacare system is sustainable and available to Canadians for generations to come.
- **Encourage innovation:** A national pharmacare program should encourage Canada's health system to innovate with new treatments and vaccines to improve patient outcomes and build a strong research and clinical trials environment that benefits Canadians and Canada's economy and competitiveness.

Further, a national pharmacare program should include the following components to enable access to a range of medicines, support patient choice and achieve a sustainable system:

- Adequate and long-term funding policies for prescription drugs to ensure Canadians can access the medicines they need in a timely manner.
- Allow Canadians to opt-in to any new public pharmacare program rather than imposing an automatic enrolment so Canadians can continue benefitting from private coverage if they prefer. This would allow governments to focus their resources on addressing coverage gaps and ensuring timely access to new medicines.
- Measures to encourage appropriate use and adherence to medicines to ensure better health outcomes and a high-performing and efficient health system.
- Mandatory review following a fixed time period to make needed adjustments.