Submission to the Study on the Patented Medicine Prices Review Board (PMPRB) Guidelines

House of Commons Standing Committee on Health

Submitted by Hoffmann-La Roche Ltd.

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About Roche Canada

Roche Canada is a subsidiary of Swiss-based life sciences company F. Hoffmann-La Roche, which is a forward-looking and highly innovative company with a longstanding commitment to investing in Canada. With the Roche Pharmaceuticals division headquartered in Mississauga, Ontario and both Roche Diagnostics and Roche Diabetes care in Laval, Quebec, we employ over 1,500 people across Canada, positioning us as a key contributor to Canada's life sciences ecosystem. In 2019, one in four Canadians were tested using a Roche diagnostic product, while Roche medicines were used to treat more than 308,000 Canadians living with conditions such as cancer, multiple sclerosis, and cystic fibrosis.

Roche Canada has directly contributed over $1 billion to Canada's GDP over the past 5 years and in 2019, our total expenditure on research and development alone totaled approximately $284 million in Canada. We also invested over $57 million in clinical research, with approximately 174 Roche-sponsored clinical trials currently underway in Canada.

Founded on the principles of innovation and collaboration, Roche is a science-based company focused on enabling better health outcomes for patients. We recognize this mission depends on the long-term sustainability of our healthcare system, which ultimately provides patients with access to our innovation. Roche plays an active role within our healthcare system and we are keen to partner with all relevant stakeholders to help build a system that is not only sustainable and equitable, but also effective and efficient; a system that is built for the needs of Canadians today and tomorrow.

Input on PMPRB's Final Guidelines

The current reimbursement framework in Canada is built on an approach which offers government and insurers various assessment and negotiation points - starting with the non-excessive pricing mandate of the PMPRB, health technology assessment (including cost-effectiveness evaluation), pricing negotiation and product listing agreements. This integrated framework in Canada has built-in checks and balances that allow the government and insurers to evaluate the price, value and patient impact of a medicine before it is reimbursed. Changing any one pillar of this framework will require a re-assessment of the entire process to ensure the system does not fail the interests and needs of patients and healthcare providers.

It is our view that the PMPRB should maintain its current role in ensuring that the price of medicines are not "excessive" in Canada based on a standardized assessment of international price comparator data. However, the final Guidelines issued by the PMPRB conflict with Justice Manson's recent decision in *Innovative Medicines Canada v. Canada (Attorney General), 2020 FC 725*, which held that the PMPRB could not consider third party rebates in exercising its mandate to regulate excessive prices. Roche Canada states that the "maximum rebated price" (MRP) concept remains in the final Guidelines, and since the MRP depends on (improper)

access to third-party payments, removal of references to MRP in the final Guidelines is required in order to comply with Justice Manson's ruling. The PMPRB therefore needs to fundamentally rethink its proposed Guidelines approach, in a way that excludes the MRP concept entirely.

If the final guidelines are implemented without the removal of references to the MRP, one of Roche Canada's key concerns is the ability to bring innovative medicines to Canada. Furthermore, Canada competes with the rest of the world in attracting clinical research investment; the pricing reforms continue to send a message that innovation and the advancement of patient-care is not a priority for Canada, thereby putting at risk our ability to compete for clinical research investments on the global stage and potentially limiting Canadian patients' early access to improvements in care.

Conclusion

Through our industry association, Innovative Medicines Canada, our industry has brought forward an alternative proposal to address affordability objectives in a manner that would preserve timely patient access, investment, and clinical trials in the future. Our industry wants to work collaboratively on a more pragmatic path forward that would balance the need for more affordable medicines with a competitive regulatory environment. Most recently, our industry offered to work with the federal government to help address the issue of rare diseases and to create a made-in-Canada manufacturing and commercialization accelerator with no response from the federal government.

With the implementation of the PMPRB changes scheduled to come into effect on January 1, 2020, Roche Canada recommends the removal of the MRP concept within the regulations. In addition, we recommend the federal government work in collaboration with provinces/territories, industry, patients, and other impacted stakeholders to have a more holistic discussion on the future of pharmaceutical policy in our country that would include pricing, national pharmacare, rare disease and the Canada Drug Agency. Roche Canada, along with our industry colleagues, remain committed to working with the federal government to find a more balanced way forward.