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Written Submission for the Pre-Budget Consultations in Advance of the Upcoming Federal Budget
By Médecins Sans Frontières (MSF) Canada / Doctors Without Borders Canada
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List of Recommendations:

Recommendation 1: That the government ensure all federal funding of health research, particularly for the research and development (R&D) of pharmaceuticals and medical devices, includes binding obligations to ensure that the recipients of such funding be required to take reasonable steps to ensure that any ensuing commercial products are affordable and accessible in Canada and around the world, particularly in low- and middle-income countries.

Recommendation 2: That the government ensure that all federal funding related to the production or manufacturing of pharmaceuticals and medical devices include binding legal obligations to ensure the products of any ensuing production or manufacturing are affordable and accessible, both in Canada and around the world, particularly in low- and middle-income countries.

Recommendation 3: That the details of all federal funding of the pharmaceutical industry, including but not limited to R&D and the construction and operation of manufacturing facilities, be made transparent, and available to the public, including the publication of contracts, funding agreements, licensing agreements, and other relevant information.

Recommendation 4: That the government should develop obligatory transparency requirements around clinical trials, including the costs of those clinical trials, for any pharmaceuticals or medical devices that have received federal funding.

Recommendation 5: That the government should establish a clear pathway to guide Canadian research to completion, from discovery through development and clinical trials to final approval, particularly where the product is of high public health importance but low commercial value, to ensure rapid patient and health system access.

Recommendation 6: That the government devote resources, such as the use of Canadian-funded manufacturing facilities, to the production of medicines with a high public health value but low commercial appeal, such as vaccines and treatments for Neglected Tropical Diseases.

Recommendation 7: That the government take appropriate measures to ensure Canadian-funded medicines and vaccines are registered in Canada, to the benefit of Canadians and others around the world, particularly in low- and middle-income countries.

Recommendation 8: That the government impose requirements on federal funding such that the rights-holder for any pharmaceuticals or medical devices developed with Canadian funding that have received market approval anywhere in the world must ensure that they are affordable and accessible in countries, particularly low and middle-income countries, where the illness or condition they address is endemic or high-burden.

Recommendation 9: That the government establish a publicly accessible platform listing all pharmaceuticals or medical devices developed or in development by Government of Canada bodies or agencies (including, but not restricted to, the National Microbiology Laboratory and the National Research Council), which would include their development status, regulatory status (domestic and international), and the status of any licenses of the technology to third parties (including the identities of those third parties).

Recommendation 10: That the government establish a publicly accessible platform tracking all pharmaceuticals and medical devices that were developed using public funding (including, but not limited to, Tri-Council agencies and Innovation, Science, and Economic Development Canada - ISED), in order to track their development status (including failure), regulatory status (domestic and international), the status of any associated intellectual property rights, and otherwise measure the impact of such funding on the development of successful health innovations.

Explanation of MSF's Recommendations

Explanation 1: Canada invests a considerable amount of public funds into health research, but the return on that investment often accrues to private for-profit entities, without fair recognition of the contributions made by taxpayers and without fair access provisions or a defined public return on this investment for patients in Canada and abroad who must pay excessively to access the fruits of such innovation. Public funding for the research and development of new medicines, vaccines, and other health technologies should be contingent on ensuring that Canadian innovation is affordable and accessible to all. These conditions should be legally binding.

Explanation 2: Canada has recently provided generous funding to pharmaceutical companies for the manufacture and production of pharmaceuticals including monoclonal antibody therapies and vaccines during the COVID-19 pandemic. However, this funding does not appear to have been contingent on ensuring the resulting products were affordable or accessible. Canadian investment should ensure affordable, accessible global pricing in Canada and in all low- and middle-income countries.

Explanation 3: The details of all federal funding of pharmaceutical research and development, including funding provided to the pharmaceutical industry, should be transparent and publicly available. This will help ensure that Canada, and Canadians, are getting a good return on the investment of public funds, rather than subsidizing a profitable industry at the expense of patients at home and abroad.

Explanation 4: Enforcing obligatory transparency requirements around clinical trials, including the costs of clinical trials, promotes accountability for public funding. It also protects patients and health systems by ensuring that prices accurately account for the legitimate costs of clinical trials.

Explanation 5: Canada currently lacks a clear pathway for end-to-end pharmaceutical development, particularly for medicines and vaccines of high public health importance but with limited commercial appeal. Examples include vaccines for public health threats like Ebola virus disease, Marburg virus disease and Lassa fever. Promising candidates for all three were developed at Canada's National Microbiology Lab; however, all three also languished on shelves for many years, due to the need to involve a third party to complete the process. Only the Ebola vaccine has received regulatory approval, and the rVSV-LASV Lassa vaccine is only now beginning human clinical trials; the unnecessary delay in getting these vaccines to the finish line has cost lives. Supporting such an end-to-end R&D and manufacturing strategy would be a logical extension of Canada's Biomanufacturing and Life Sciences Strategy.

Explanation 6: Canada is investing in manufacturing facilities, including both publicly owned and privately owned (e.g., Sanofi) facilities. Particularly when not needed to respond to the COVID-19 pandemic, publicly owned facilities should be used to produce medicines of high public health value but low commercial appeal, to improve global access to needed medicines. This will keep these facilities from being sitting idle or being sold off, will not compete with commercial interests (which do not make these products, resulting in what is essentially a market failure for many medicines – such as antibiotics and others), and offer Canada opportunities to position itself as a global health leader by producing sought-after products of public health importance.

Explanation 7: The registration of Canadian-funded drugs in Canada benefits more than just Canadians. Successful registration of a pharmaceutical product with Health Canada, a Stringent Regulatory Authority, provides a mechanism for ensuring global access in countries that depend on either World Health Organization pre-qualification or registration by a Stringent Regulatory Authority. Ensuring that medicines and vaccines developed in whole or in part with Canadian public funding be registered for use in Canada (there is currently no requirement that medicines developed with Canadian funding be registered for use in Canada) thus serves a useful function for global access.

Explanation 8: The fruits of Canadian health innovation should be available and affordable to everyone, no matter where they are located. As such, Canada should ensure these binding requirements extend beyond Canada's borders, particularly to low and middle-income countries where the illness or condition in question is a serious health concern.

Explanation 9: Canada has made important discoveries (like the Ebola virus vaccine) that have languished on shelves. Part of the problem is that there is no accessible database of Canadian innovations, providing information on development, regulatory status and licensing status. A transparent database will make this information clearer to the government (by identifying which promising innovations need more attention), to the public, and to prospective developers/licensees of these technologies. This would also support initiatives to promote Canadian end-to-end development and Canadian manufacturing of biotechnologies, and should be aligned with initiatives to promote and enhance open science approaches for drug and vaccine development.

Explanation 10: Currently, the impact of Canadian public funding on health innovation is unclear. This includes both a lack of clarity about successful investments and about unsuccessful ones. Better tracking of the outcomes of funding from the Tri-Council agencies, Innovation, Science and Economic Development Canada (ISED) and other parties will help to identify gaps and areas where public investments have delivered impactful medicines, vaccines, and other health technologies and clarify the impact of these investments.

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