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Submission to the Standing Committee on Finance's Pre-Budget Consultations in Advance of the 2024 Budget

August 04, 2023

Category: Health Research, Development & Production

Recommendation 1: Ensure all federal funding a) of health research, particularly for research and development (R&D) of pharmaceuticals and medical devices, and b) related to production or manufacturing of pharmaceuticals and medical devices includes binding obligations requiring funding recipients to take reasonable steps to ensure any ensuing commercial products are made affordable and accessible in Canada and elsewhere, particularly in low- and middle-income countries (LMICs).

Recommendation 2: Ensure details of all federal funding of the pharmaceutical industry, including but not limited to R&D and construction/operation of manufacturing facilities, be made transparent and publicly available, including publication of contracts, funding agreements, licensing agreements, and other relevant information.

Recommendation 3: As part of any funding allocations to the Canadian Institutes of Health Research Clinical Trials Strategy, develop obligatory transparency requirements around clinical trials, including their costs, for any pharmaceuticals, medical devices, or other health technologies.

Recommendation 4: Establish a clear funding pathway to guide Canadian research, 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 5: Commit at least $5 million to manufacture one or more medicines or vaccines, including using Canadian-funded manufacturing facilities, with a high public health value but low commercial appeal, for use during public health emergencies such as Ebola outbreaks and make them available to Ministries of Health and humanitarian organizations free of charge or on a cost-recovery basis.

Recommendation 6: Impose requirements on federal funding and take whatever other measures necessary to ensure Canadian-funded medicines and vaccines are registered in Canada and LMICs.

Recommendation 7: 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 status of any licenses of the technology to third parties (including identities of those third parties).

Recommendation 8: Establish a publicly accessible platform tracking all pharmaceuticals and medical devices 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

(Category: Health Research, Development & Production)

Explanation 1: Canada invests considerable public funds into health research. The return on that investment often accrues to private for-profit entities, without fairly recognizing the contributions made by taxpayers and without fair access provisions for patients (including in Canada) who are increasingly paying unaffordable prices for lifesaving medicines and vaccines. Canada has recently provided generous funding to pharmaceutical companies for the manufacture 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 affordability or accessibility of the final products. Public funding in Budget 2024 for the development of new medicines, vaccines, and other health technologies, and investment in the production and manufacturing of these technologies should be contingent on ensuring that Canadian innovation and production is affordable and accessible to all. These conditions should be legally binding.

Explanation 2: The details, including contracts, of all federal funding of pharmaceutical research and development in Budget 2024, including funding provided to the pharmaceutical industry for manufacturing/production 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 3: Enforcing obligatory transparency requirements for individual clinical trials, including their costs, promotes accountability for public funding. It also protects patients and health systems by ensuring prices accurately account for the legitimate costs of clinical trials.

Explanation 4: 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 Canadian-discovered vaccines for public health threats like Ebola, Marburg virus disease and Lassa fever. Promising candidates for all these were developed at Canada's National Microbiology Lab; however, they all also languished on

shelves for many years, due to the need to involve a third party to complete the process. More than 20 years after discovery, only the Ebola (Zaire) vaccine has received regulatory approval, and the rVSV-LASV Lassa and rVSV-SUDV Ebola (Sudan) vaccines have only recently entered human clinical trials. The unnecessary delay in getting these vaccines to the finish line has cost lives. Supporting an end-to-end R&D and manufacturing strategy would be a logical extension of Canada's Biomanufacturing and Life Sciences Strategy.

Explanation 5: Canada is investing in manufacturing, 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 domestic and global access to needed medicines. This will keep these facilities from sitting idle or being sold off, will not compete with commercial interests (which lack interest in low-profit high-need products, resulting in what is essentially a market failure for many medicines), and offer Canada opportunities to position itself as a global health leader by producing sought-after products of public health importance such as Ebola monoclonal antibodies listed as Essential Medicines by the WHO. $5 million could provide access to treatment for thousands of exposures and high-risk contacts.

Explanation 6: 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 such requirement) thus serves a useful function for global access.

Explanation 7: Canada has made important discoveries (like the Ebola virus vaccine) that have languished on shelves. Part of the problem is 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 pharmaceutical development.

Explanation 8: Currently, the impact of Canadian public funding on health innovation is unclear. This includes a lack of clarity about both successful and unsuccessful investments. Better tracking of 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.

Category: International Assistance

Recommendation 9: Continue to demonstrate Canada's commitment to meeting the needs of people around the world affected by acute emergencies such as conflict, displacement, and natural disasters, by ensuring its spending on international assistance towards humanitarian action in 2024-25 either matches or exceeds the peak level of $1.16 billion previously allocated in 2020-21.

Recommendation 10: Maintain Canada's commitment to improving access to essential healthcare for the people of South Sudan by ensuring the Health Pooled Fund (HPF) will be replaced by a more effective and accountable donor-supported health-financing mechanism that will deliver improved health outcomes without interruption when the current HPF funding cycle expires in March 2024.

Recommendation 11: Continue to play a leadership role in the global response to the Rohingya displacement crisis by allocating funding to a new phase of Canada's Strategy to Respond to the Rohingya and Myanmar Crises that is equal to or greater than the value of Canada's current commitments.

Explanation of MSF's Recommendations (Category: International Assistance)

Explanation 9: As Canada has itself noted in its most recent Report to Parliament on the Government of Canada's International Assistance (2021-22), "[t]here is an unprecedented level of humanitarian need in the world today. This is due to increases in the number and intensity of armed conflicts as well as the scope and frequency of natural disasters as the result of climate change." As a humanitarian actor, MSF has witnessed both these growing needs and the increasing gap between those needs and the global humanitarian response, with the failure of humanitarian assistance budgets around the world to adequately address sudden-onset humanitarian emergencies. Last year, MSF's own operational expenses increased 22% between 2021 and 2022 because of increased needs. As a mostly privately funded humanitarian actor, we have also frequently found ourselves responding alone to humanitarian emergencies because there is not enough institutional funding available for other humanitarian responders to act. As a crucial humanitarian donor, Canada must continue to prioritize the ability to respond to acute humanitarian needs as an essential part of its overall international assistance budget in 2024, in contrast to the reduction in Canada's international assistance towards humanitarian action spending from a high of $1.16B in 2020-21 to $1.045B in 2021-22.

Explanation 10: Canada is an essential supporter of the Health Pooled Fund, the funding mechanism South Sudan's public health system currently depends upon to provide essential medical services in eight of the country's ten states. The current HPF funding phase (HPF3) will end in 2024 and will not be renewed, potentially leaving millions of people without access to even basic levels of healthcare unless Canada and other donors establish a replacement mechanism. It is crucial that such a replacement not only provides uninterrupted continuity of health services but also sufficient oversight and accountability for all stakeholders to deliver

improved healthcare. As a major donor and supporter of health financing in South Sudan, Canada can and must play a leadership role among donor partners, to ensure that vulnerable people in South Sudan can have access to lifesaving medical care.

Explanation 11: Almost six years since organized violence drove hundreds of thousands of people from Myanmar's Rohingya ethnic minority into Bangladesh, more than one million Rohingya refugees remain confined to overcrowded displacement camps and squalid living conditions in Cox's Bazar, Bangladesh. Denied citizenship in Myanmar and unable to work legally in Bangladesh, most of these refugees are entirely dependent on humanitarian assistance for survival, including for food, clean water, shelter and medical care, or must make risky choices to earn money without legal protections. But after an initial outpouring of global generosity from countries like Canada in the early days of this emergency in 2017, international assistance, donor commitments and political efforts are now rapidly reducing. It remains deeply unsafe for Rohingya refugees to return to Myanmar and no other immediate solution to their situation is evident. Meanwhile, many Rohingya communities remaining in Myanmar are confined to dismal detention centres and all lack basic rights. Canada has played an important leadership role in the global response to the Rohingya's humanitarian needs since 2017. Since its first phase in 2018 (followed by a second phase announced in 2022) Canada's Rohingya Strategy has played a vital role in alleviating the suffering of the Rohingya people. But that work remains incomplete and beset by new challenges, especially as the difficulties faced by Rohingya refugees only increase, funding from the global community decreases, and solutions to the situation remain elusive. For these reasons, Canada must maintain its commitment to the Rohingya people and renew its Rohingya Strategy for a third phase, with necessary financing, starting in 2024.