

**Submission to the Standing Committee on Health  
Study on Federally Funded Health Research (M-132)  
October 2018**

**Background**

Doctors without Borders / Médecins Sans Frontières (MSF) is an independent, international medical humanitarian organization that delivers medical care to people in over 70 countries. Our work focuses on the medical needs of vulnerable people, whose needs are often neglected. In 2017 MSF conducted more than ten million outpatient consultations, provided HIV treatment to more than 215,000 people, started more than 20,000 people on tuberculosis treatment, and treated more than 2.5 million cases of malaria.

As a medical humanitarian organization, MSF needs both affordable access to and innovation for medical technologies. Yet, for more than 40 years, MSF teams have witnessed the deadly consequences of people being unable to access the lifesaving drugs and health products such as vaccines, diagnostics, and other medical devices, that they need, either because they are too expensive, are not adapted to local health care settings, or simply do not exist.

MSF is making this submission to the Standing Committee on Health (HESA) to provide our perspective on how Canada, as one of the major funders of health research in the world, can improve the ways in which drugs and other health products (medical devices, diagnostics, vaccines, etc.) are developed with public funds and made available to people and health systems that need them. The current study presents an historic opportunity for Canada to review and adapt its approaches to health research to ensure it has the appropriate policies and principles in place to develop and deliver affordable drugs and health products that respond to the health needs of people everywhere.

**General Principles – A Health Research and Development System That Prioritizes Access and Affordability**

Publicly-funded health research should be structured to prioritize and address unmet health needs globally and deliver affordable and accessible medical tools and knowledge. Achieving this in a meaningful way requires a biomedical innovation system that prioritizes therapeutic innovations and improvements, a research and development (R&D) financing structure that is transparent and separate (“delinked”) from the final price of products, that prioritizes access and affordability, and which reflects and transparently reports the collective investment and risk-taking involved by the public and private sectors, civil society, patients, and others.<sup>1</sup> This requires a clear articulation of not only the desire, but the ways in which to improve health outcomes through policies that ensure funders of health research are maximizing the use of public funds to deliver public goods.

CIHR, the main funder of biomedical research in Canada, has a mandate that includes to “excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system.”<sup>2</sup> Although health products – such as drugs, devices, vaccines, and other medical devices – are included in this definition and may be discovered with CIHR funds, we are unaware of the Institute having a policy that requires recipients of public funds to ensure that Canadian and other patients will have access to the products that are developed with the funds that it provides, even when those products may offer the potential for “improved health for Canadians” or other patients around the world.<sup>3</sup> CIHR’s Commercialization and Innovation Strategy<sup>4</sup> similarly lacks such a safeguard, instead focusing on the economic benefits of commercialization. Put simply: there is no safeguard that ensures that products discovered or developed with public funds would be affordable for Canadians or other patients around the world.

Ensuring a public return on public investment should be a guiding principle of Canadian health research. In the context of the development of drugs, devices, vaccines, and other health products, this should translate into timely, affordable access to products discovered and/or developed in whole or in part with Canadian public funds. Profitability – for research institutes, for investigators, or for the Government of Canada – should not be a guiding principle behind decisions on how or whether to develop or commercialize health products.

The fundamental issue is not just high prices. High prices are a symptom of a broken health research and innovation system. The fundamental issue is how this system is working and the outputs it's producing. The problem is clear: the business model that underpins health research and innovation systems is not delivering drugs and other health products that are affordable and that address global public health priorities. If we want different outputs, we need a different model. MSF recommends the following:

#### Prioritize and Create Incentives for Canadian Health Research to Develop Accessible and Affordable Health Products

Canada has the ability to prioritize health research that responds to public health needs, and does so through a number of pathways including the CIHR Priority-Driven Research Initiative (which encompasses approximately one quarter of CIHR's budget),<sup>5</sup> research at the National Microbiology Laboratory to track, diagnose, prevent, and treat the spread of infectious diseases,<sup>6</sup> and the creation of a vaccine research and development priority list,<sup>7</sup> among others. Investigator and public health needs-driven research conducted with public funds has resulted in highly impactful medical advances from Canadian publicly-funded investigators. However, the predominant mechanism by which these innovations move out of labs and into the drug (or device) development pipeline is through commercialization – licensing or sale to private sector entities whose contribution to the subsequent product development is masked by a lack of transparency in their costs and investments.

Canada should consider models of development that “delink” the costs of R&D from the price of the end product. This principle (delinkage, or the concept of separating the cost of investments in R&D from the price and volume of sales) has been applied to eliminate the requirement to recoup R&D investments or finance future research through the sale of products or revenues generated by intellectual property (IP) and is contained in several political declarations to which Canada participated.<sup>8,9</sup> In a delinked model, public and private contributions pay for the cost of R&D upfront, allowing researchers and developers to independently identify needs, gaps, and priorities based on patient needs, to promote the sharing of research knowledge and data, and to price products at the lowest sustainable price that ensures access. To effectively delink the cost of R&D from the final price of the product, Canada could consider the use of new models for developing drugs and health products contained in one of its priority lists (noted above), including the use of incentives other than royalties derived from sales for entities that develop them. Once priorities are identified, Canadian public funders should think through the steps that are needed to develop and deliver new health products to address them, from discovery through development and delivery – start to finish. Funders or other entities could act as the coordinator of needed innovation, adopting a “mission-oriented approach” that includes the use of Canadian models of product development partnerships that leverage the expertise and investments of government, universities, industry, and civil society to develop new drugs and health products to address the priorities.

Canada could move toward an integrated discover-develop-deliver pathway/framework that includes the use of product development partnerships (PDPs) to leverage the expertise of civil society, universities, industry, and others to develop and deliver new health products. CIHR and other entities with priority-driven research funding could include the use of both grant-based operating funds to stimulate and support needed health research, and the use of prizes when specific milestones are reached (e.g. clinical trial registration, product registration, etc.) to replace royalties obtained through exclusive licensing agreements, and incentivize participation in alternative mechanisms of drug or health product development.

MSF has experience with PDP models, specifically the Drugs for Neglected Diseases *initiative* (DNDi), which has successfully brought several new drugs, fixed dose combinations, and pediatric formulations to market since its inception. This model creates a framework for collaboration among the actors involved to better leverage research investments to more efficiently address public health priorities and could be considered for other therapeutic areas where access and affordability are of concern, guided by appropriate policies and principles

**Recommendation 1:** Canadian funding agencies should develop new pathways for health research and innovation that are capable of discovering, developing, and delivering new health products and which prioritize access and affordability, by:

- Creating Canadian product development partnerships, or supporting existing ones, that can support the development of drugs, vaccines, diagnostics, and medical devices, including pre-clinical through to clinical trials and obtaining product registration in all countries where a need exists, guided by principles of access and affordability.
- Creating incentives that delink the cost of research and development from the final price of drugs and health products, such as providing sustainable and adequate funding for a partnership-based development process and the use of prizes to reward researchers who reach certain milestones in product development (e.g. registration of clinical trials or new chemical entities) and who agree to license the products to developers, with access and affordability principles to ensure the final products are available to patients who need them.

#### Develop Access Plans for Medical Tools

A renewed approach to publicly-funded health research should include safeguards that result in fair pricing of new health products that result from this funding. Evidence demonstrates there is no direct connection between the resources invested in R&D by pharmaceutical companies and the price they charge for medicines, although this serves as a common justification for high prices. We are not aware of specific data or analyses on the number of drugs, devices, or vaccines that have been brought to market after having been developed in whole or in part with Canadian public funds, however previous analyses evaluations by CIHR show that at least 42 different spin-off companies were created or benefitted from CIHR Proof of Principle funding between 2001-2015.<sup>10</sup>

Canada could be negotiating a better deal for all people who need access to medicines, including Canadians, that are developed with public funds, by requiring recipients of public funds to have access and affordability policies in place for discoveries that are made with public funds. For example, grants could include a requirement for recipients to have an access plan for new discoveries that includes the steps a recipient of public funds or a company that obtains the rights to a health product developed or discovered with public funds commits to take to enable the timely registration and availability of the product at an affordable price in Canada and in every county with a demonstrated need (e.g. high burden countries, endemic presence of disease, or other criteria).

The University of British Columbia (UBC) is one of the first universities in the world to implement such a strategy for global access licensing of its products. UBC's global access principles<sup>11</sup> are implemented through the university's university-industry liaison office and are designed to ensure that people and health systems have "at cost" access to UBC-developed innovations through negotiated global access terms. The university utilizes a variety of mechanisms to do this, including the issuing of non-exclusive licenses, the use of field-of-use and jurisdictional limitations in exclusive licenses to exclude developing countries, and the use of partnerships with not-for-profit entities for subsequent development and delivery. Implementing a version of these principles could be required of all grant recipients and institutions receiving public funding and applied to innovations developed or discovered with public funds. The creation of product development partnerships described above could then fulfill the need to bring stakeholders together to develop and deliver the product through an R&D model whose costs would be delinked from the final price of the product, allowing for enhanced oversight and negotiation of fair pricing strategies early on in the development process.

**Recommendation 2** – Federal funding agencies, like CIHR and others, should implement requirements that recipients of public funds have access and affordability policies in place for discoveries that are made with public funds. This could be achieved by including in CIHR's Institutional Eligibility Requirements a requirement to have institutional policies, plans and principles in place to better ensure that publicly-funded discoveries are affordable, globally accessible, registered in countries that need them, and that the science used to develop them is made available for others to build on. This could be done through the development and implementation of global access principles to be applied across institutions, and potentially included in Requirement 3 (Compliance Requirements) of CIHR's Institutional Eligibility Requirements.<sup>12</sup>

#### Increase Transparency

Reliance on patents and market exclusivity as an incentive for health research to develop drugs and health products pushes scientists and companies to work in isolation from, and in competition with, one another. Researchers may repeat the same mistakes and are unable to benefit from the advancements of scientific knowledge in a timely way. Clinical data reporting currently suffers from incentives for selective reporting and an undermining of comprehensive knowledge of safety and efficacy. The result is a system that is slower, less efficient, less safe and effective, and more expensive.

The three Canadian federal granting agencies (the Agencies) that promote and support research, research training, and innovation in Canada have a harmonized policy requiring the findings of research conducted with funds from the Agencies to be made available through open access publications.<sup>13</sup> Similarly, the Agencies provide a set of guiding principles on making research results “... as widely available and accessible as possible is an essential part of advancing scholarship, promoting intellectual inquiry and critical analysis, and applying knowledge to ensure that practical solutions are found to challenges facing Canadians.”<sup>14</sup> CIHR has made further commitments to expand on the sharing of health research and health-related data, including developing and adopting policies to support the effective stewardship and sharing of data generated and used for research.<sup>15</sup>

Biomedical research and development costs money and involves risks, but how much it costs to develop a drug or other health product is not clear because the global data are rarely available and companies aren't transparent with their actual costs, including the various subsidies and tax benefits that accrue to companies conducting particular forms of R&D. Instead, policymakers and the public are forced to rely on estimates, generally provided by industry themselves. Public scrutiny of agreed upon targets for pharmaceutical R&D in Canada has consistently shown that the percentage of R&D-to-sales by pharmaceutical companies in Canada has been under the agreed-upon target of 10% since 2003, and has been falling since the late 1990's. In 2017, the Patented Medicines Price Review Board (PMPRB) found that the percentage of R&D-to-sales by pharmaceutical companies was only 4.1% for all patentees.<sup>16</sup> Moreover, while industry claims that it costs billions to develop a new drug or vaccine, published evidence<sup>17</sup> and the experience of others such as DNDi, suggests these costs can be significantly lower when alternative models of R&D, including product development partnerships, are used.

**Recommendation 3** - Greater transparency on the costs and risks of medical innovation and the costs of manufacturing would help inform the ongoing efforts to see how we can better deliver products that meet public health needs and are accessible to people who need them. It is important to understand the true costs of innovation to know how to improve or create new appropriate incentives that will deliver more efficient and effective innovation accessible to populations in need. Canadian public funders could include transparency requirements in funding agreements to require funding recipients to provide clear, disaggregated and verifiable information on R&D and manufacturing costs throughout the product development process (including by those acquiring rights to the product) so as to increase transparency across the system and contribute to knowledge of the true cost of developing new medicines and other health products.

### Conclusion

The high prices of medicines, vaccines and diagnostics is now recognized as a global issue, threatening people's access to the health products they need in countries of all economic classifications. It is a global issue not only because it affects people on every continent, but also because addressing it requires countries to develop and implement proper policies, both domestically and internationally.

Canada has enacted several important policies recently that could contribute to a framework for reviewing its approaches to biomedical innovation so as to better ensure access to the technologies, innovations, and knowledge developed with public funds, including a renewed Innovation Agenda, increases in federal funding of science in Budget 2018, the Fundamental Science Review, the Feminist International Assistance Policy, and others.

Harnessing Canadian innovation and health research potential to direct it toward a mission-oriented approach that develops and delivers new health products for addressing pressing global public health priorities requires national and international efforts to identify problems and invest in solving them over the long-term. Moreover, it requires Canada to have the policies in place to not only fund health research but to also take responsibility for the subsequent development of products discovered with public funds and ensure the sharing of knowledge and discoveries between researchers and entities capable of developing and delivering them to patients quickly, affordably, and equitably.

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