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Submission to Clinical Trials Modernization Consultation
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Introduction

Doctors Without Borders/Médecins Sans Frontières (MSF) is an international medical humanitarian organization that provides impartial medical assistance to people affected by armed conflicts, natural disasters, disease epidemics, malnutrition crises and other emergencies. In 2019, more than 65,000 staff from MSF provided medical assistance to people in more than 70 countries. Our teams carried out over 10.3 million outpatient consultations, treated more than 2.6 million cases of malaria, and cared for hundreds of thousands of people on first-line antiretroviral therapy for HIV. We're also the largest non-governmental provider of tuberculosis (TB) treatment in the world, and last year started thousands of people on first line treatments for TB and drug resistant TB.

To deliver high-quality medical care, MSF needs both affordable access to and innovation for drugs and other health products like diagnostics, vaccines, and medical devices and have worked for decades to push for more affordable access to them and for health research systems that prioritize public health needs. MSF is not a passive observer in this process. Our teams are actively involved in conducting and supporting clinical trials as subject matter experts and as trial sponsors, and our medical teams depend on timely and transparent access to trial results to guide our decision-making in the field. Given this in-depth involvement, we can provide the following inputs to Canada's consultation on clinical trials modernization.

The focus of this submission is clinical trial transparency. MSF is encouraged to see that transparency is a consideration within this consultation. However, this principle should be extended, and the ensuing obligations made obligatory and enforceable.

Binding Transparency Obligations Needed

Broadly speaking, MSF believes that transparency should be rooted in binding obligations rather than purely voluntary efforts. For instance, even if the voluntary registration of trials results in a high degree of compliance, it is insufficient as some important trials and their results remain undisclosed and inaccessible, potentially resulting in reporting biases that may impact patient and provider choices and decisions. As such, MSF would encourage the development of binding regulatory measures going beyond simply policy-based solutions. These obligations should apply both to pharmaceuticals and other areas like medical devices.

International Trial Registration

The obligatory registration of trials in international databases is a useful measure. The standards proposed for an eligible registry are reasonable.

Ties to Research and Other Funding

Another area deserving of more (ideally) regulatory or (less ideal but still useful) policy attention would be strengthening the links between public funding and transparency obligations. These should be in addition to other transparency measures. A consistent concern regarding multiple streams of public funding is that said public funding frequently comes with few if any conditions attached to ensure that final products (medicines, vaccines, etc.) are priced affordably and made globally accessible. MSF's medical teams have repeatedly been faced with situations where effective treatments or vaccines, including those discovered and developed with public funding, were priced out of reach of patients and health systems and, therefore, inaccessible to patients. A frequent justification for these high prices is that companies need to recover their research and development costs; however companies have historically been reticent to make such cost data available for scrutiny. As a result, patients are denied access to medicines that are priced out of their reach, a pricing and sales scheme

that ostensibly justified by very high costs, that in turn are never actually disclosed. Transparency obligations should be a requirement of all government funding, from any government body. Although research funding (e.g., CIHR) is one important area where this should occur, binding transparency obligations should not be restricted to this area. For instance, funding from other bodies like ISED should be contingent on the recipients meeting transparency obligations in their operations.

Transparency re: Clinical Trial Costs

One particular area where transparency is important, but is currently missing from this proposal, is in the area of clinical trial costs. There have been proposals, for instance in the United States, to include this information directly within the clinical trials database. Particularly in the pharmaceutical field, where high costs are used as a justification of high prices, transparency over the actual costs of clinical trials will help to resolve this issue. We would emphasize that this is a neutral measure; where transparently revealed costs need to be recouped, this is indeed a legitimate pricing consideration.

Public Disclosure of Results, and of Clinical Trial Protocols

Regarding other areas of transparency that are discussed, transparency measures around trial results will help address issues such as publication bias and outcome reporting bias. Disclosure of such results must be timely. Furthermore, these transparency measures should be designed to clearly encompass Clinical Trial Protocols as well as results, so that what is actually being assessed is as clear as the outcome. The ability to assess robustness and rigor are important. These measures will also reduce unnecessary duplication of scientific efforts.

Consideration of Foreign Standards

It will also be important for Canada's standards to reflect those of other countries, even if foreign transparency measures should be considered a minimum standard, not a maximum. For instance, in the United States, there is increasing legislative interest in transparency into R&D costs. Bipartisan legislation has been introduced that would require manufacturers to disclose R&D costs in justification of certain price increases. Lawmakers from both parties have advanced bills to establish detailed accounting of how taxpayer dollars are being spent in the development of COVID tools and there are indications that others are considering proposals to mandate cost disclosure for federally funded clinical trials of medical tools more broadly. Canada should monitor such activities in the United States and elsewhere in developing its own clinical trial transparency measures, giving due consideration to the importance of aligning with foreign developments, while also ensuring that foreign standards are considered a floor, not a ceiling, for transparency.

Accessibility of Information

Finally, as contemplated in this consultation, measures to improve access to the information yielded by improved transparency initiatives are also important. Readily searchable databases, easily accessible to interested parties from academics and fellow researchers, to CSOs, to the general public, would be valuable.