

Medicines for Malaria Venture

Pre-Budget Submission

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Executive Summary

Medicines for Malaria Venture (MMV) is pleased to contribute to the pre-budget consultation process of the Parliament of Canada's House of Commons Standing Committee on Finance for the 2018 Federal Budget. MMV is a leading product development partnership (PDP) in the field of antimalarial drug research and development. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and delivering new, effective and affordable antimalarial drugs.

Since its foundation in 1999, MMV and partners have developed and brought forward six new medicines. MMV and partners manage a portfolio of 65 projects, the largest portfolio of antimalarial research and development (R&D) and access projects ever assembled. The portfolio includes nine new drugs in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria, and drugs that could support the elimination/eradication agenda. MMV's success in research and access and product management comes from its extensive partnership network of over 400 pharmaceutical, academic and endemic-country partners in more than 55 countries.

MMV's vision is a world in which innovative medicines will cure and protect the vulnerable and underserved populations at risk of malaria, and ultimately help to eradicate this terrible disease. Malaria disproportionately impacts women and girls. With Canada's renewed focus on women and girls in international development, we believe that the time is right for a new partnership with Canada to fight AIDS, tuberculosis (TB) and malaria. Such a partnership would be grounded in Canada's strengths in R&D, science and medicine, and assist Canadians in becoming more productive. This partnership could also help catalyze innovation as a driver of economic growth in the health and biosciences sector – one of the focus areas of the federal government's Super Cluster Strategy.

In this connection, MMV would respectfully recommend that Canada allocate a minimum equivalent to 5 per cent of its Global Fund pledge towards R&D to advance the fight against the three diseases which would generate over \$4 million in research funding per year, per disease area (AIDS, TB and malaria). Having seen the significant success of the PDP model, such investment would support the Global Fund and its beneficiaries in their works to control and in some cases eradicate these diseases. This is especially important in light of increasing anti-microbial resistance to known and effective drugs to treat these diseases, especially in pregnancy.

Introduction

Canada is a global leader in promoting gender equality and the empowerment of women and girls, as most recently expressed in its new feminist international assistance policy. By the year 2021-22, at least ninety-five per cent of Canada's bilateral international assistance will target or integrate the advancement of gender equality and the empowerment of women and girls. The federal government's aid plan will direct at least 50 per cent of bilateral assistance to sub-Saharan African countries to advance gender equality and improve the quality of life of women and girls. Canada will help to ensure that the poorest and most vulnerable have access to quality health care by extending aid to traditionally marginalized members of society in the developing world.

In this connection, every day, 720 children, nearly one child every two minutes, will die of malaria. Globally, malaria-related deaths are highest in pregnant women and children under the age of five¹. In fact, malaria remains one of the top three killers in the context of maternal, newborn, and child health, and the associated risks are lifelong for those in endemic regions. Malaria interferes with the ability of

¹ The threat of artemisinin resistance to Africa: Are we prepared? http://www.wwarn.org/about-us/news/threat-artemisinin-resistance-africa-are-we-prepared

women to participate in the economic development of their communities as they care for their sick children, and hinders any attempt to improve their quality of life. Likewise, when pregnant women contract malaria, their newborns are destined for a life of unrealized potential as the consequences of malaria carry over into slower child development. It is a tragic cycle of poverty and disempowerment for women as they carry a disproportionate weight of malaria on their shoulders.

Despite some formidable results over the past 17 years, malaria continues to be a serious global challenge. Although the malaria mortality rate was reduced by 60 per cent since 2000, in 2015, malaria infected over 200 million people globally and took the lives of 429,000 individuals, an estimated 303,000 of which were under the age of five, including 292,000 children in Africa.²

The Government of Canada's international assistance programming is in line with the UN's Agenda for Sustainable Development, which includes ending the malaria epidemic by 2030. Canada's contribution towards the Global Fund is an important step in that direction however it is not enough: the World Health Organization (WHO) milestone for malaria mortality reductions by 2020,³ established to ensure adequate progress towards elimination by 2030, already looks unlikely to be reached.

Canada could be part of a solution that not only advances its international assistance objectives but also strengthens its global leadership in R&D, innovation and medicine. For example, similar to Canada's recent contribution to the Global Polio Eradication Initiative⁴, Canada could contribute to programs that will discover and deliver anti-malarial medicines for women and children. With innovative funding programs targeting women and children, and a pre-existing network of Canadian partners, MMV is well positioned to support Canada in this endeavour and help underpin its commitment to the Global Fund.

1. What federal measures would help Canadians to be more productive?

Canadian scientists are vital stakeholders in global R&D, but despite Canada's world-class medical research capabilities, federal R&D involvement in the fight against malaria is limited. For instance, no Canadian university, private sector company or research institute is currently listed amongst Roll Back Malaria's primary partners on malaria.

For its part, MMV is currently working with Canadian researchers, as well as Canadian NGOs on new field-based initiatives designed to build and strengthen local health systems to facilitate R&D and adoption of medicines. With direct Canadian investment in MMV, the Government would be in a strong position to advocate for deepening relationships with the Canadian NGO and research communities.

Beyond funding, supporting MMV is an effective way to leverage other forms of outreach to the scientific community. For example, MMV's Expert Scientific Advisory Committee, convenes annually to review progress in its medicine development projects, to share scientific knowledge and raise awareness among local scientists. In June 2016, MMV co-hosted the Malaria Symposium with McGill University and the Structural Genomics Consortium in Montreal. In September 2016, as part of the Global Fund Replenishment Conference, MMV hosted an 'Impact Dialogue' with government policy-makers and key opinion leaders on how renewed political commitment and financing can help defeat malaria. These

² http://www.who.int/malaria/media/world-malaria-report-2016/en/

³ Global Technical Strategy for Malaria 2016-2020: http://www.who.int/malaria/publications/atoz/9789241564991/en/

⁴ Canada will contribute \$100 million over three years to the Global Polio Eradication Initiatives' Endgame Strategic Plan, which seeks to wipe polio out for good by 2020. This aligns with Canada's leadership on gender equality within global health by helping ensure equal access to needed vaccines and interventions for both girls and boys and by engaging women as community social mobilizers and front-line health workers.

efforts give Canadian scientists the opportunity to be at the forefront of science and innovation in the fight against global epidemics.

Federal support to groups like MMV, and similar PDPs related to AIDS and TB, would direct vital Canadian funding to a wide range of innovative scientific organizations with technical expertise to build upon Canada's traditional development partnerships. The government could leverage such financial contributions to further cement these ties, and help ensure that Canada's global prowess in fundamental scientific research and innovation is utilized to advance new life-saving medicines for diseases that affect the most vulnerable, and help maximize the country's scientific knowledge pool.

2. What federal measures would help Canadian businesses to be more productive and competitive?

With its three-year, \$785 million CAD commitment to the Global Fund to Fight AIDS, TB and malaria in 2016, Canada is already contributing to the global fight against malaria. Hosting the Global Fund Replenishment Conference further demonstrated Canada's commitment to fighting the three diseases. However, recent gains in malaria control are jeopardized by rapid increases in insecticide and drug resistance. For example, parasite resistance to artemisinin, the core compound of the best available antimalarial medicines, has been detected in 5 countries in the Greater Mekong region of South East Asia. if the Global Fund is to continue to have a useful basket of tools at its disposal and deliver on its goals, that investment must be bolstered by a continued support of upstream activities.

Vital in the effort to fight malaria is the need to continually introduce new technologies to treat, prevent, and intercept the transmission of malaria. New medicines are required to counteract the spread of drug resistance, as documented in South East Asia. Alongside improved diagnostics, vector control, and other technologies and medicines that address unmet medical needs are critical. To maintain a robust pipeline capable of meeting these demands, an additional amount of approximately \$673 million per year is needed until 2030 to fund malaria research and development. While there is a large market for these new tools they are not very profitable, which makes conventional financing a challenge. The estimated resource needs for global malaria elimination and eradication far outstrip their availability. In an era when traditional overseas assistance levels are stagnating, it will prove very difficult to meet funding requirements through existing traditional development channels. The bulk of the burden for raising new funds will fall to developing countries, but they cannot meet those targets alone.

Over the last eight years, MMV has invested more than \$1,700,000 CAD in more than a dozen research institutions and Canadian pharma partners. MMV has been working with Canadian NGOs on field-based initiatives designed to build and strengthen local health systems to facilitate R&D and the adoption of medicines. Together with Aga Khan Foundation Canada (AKFC) and Global Affairs Canada, MMV will conduct qualitative research in the Mopti region of Mali to understand gaps in the management of malaria for women and children under the age of five. The research findings will serve strengthen malaria prevention and treatment practices in the regions informed by WHO policies and ultimately reduce malaria mortality among women of reproductive age and children under the age of five. MMV is currently exploring options for collaboration with Grand Challenges Canada.

Organizations such as Grand Challenges Canada, Canadian NGOs and the Canadian Institutes of Health Research are funding important malaria programs. R&D is an area where Canada could further leverage its world-class scientific expertise and play a much more pivotal role in the fight against global epidemics. Canadian scientists are vital stakeholders in global R&D, but despite Canada's world-class medical research capabilities, federal R&D involvement in the fight against malaria is limited. For example, a

review of the donors for 10 major, multi-donor PDPs focused on diseases affecting the poor⁵ reveals that Canada and Italy were alone among the top 10 OECD-Development Assistance Committee donors to have no current funding footprint with these institutions.

Federal support to groups like MMV would direct vital Canadian funding to a wide range of innovative scientific organizations with technical expertise to build upon Canada's traditional development partnerships. The government could leverage such financial contributions to further cement these ties, and help ensure that Canada's global prowess in scientific research and innovation is utilized to advance new life-saving medicines for diseases that affect the most vulnerable, and help maximize the country's scientific knowledge pool.

Innovative funding models, like MMV's, that raise funding and in-kind contributions from public, private and philanthropic sectors, will be increasingly necessary to meet these goals. MMV has been able to leverage approximately \$2.50 for every \$1 of donor funding in matched funding and in-kind support from academic and industry partners. This model aligns with Canada's desire, outlined in the Feminist International Assistance Policy, for further collaboration with private sector and non-traditional aid partners and for increased investments in research.

By sharing its cutting-edge scientific expertise and facilities with PDPs focused on developing new interventions for poverty-related infectious diseases, the Canadian research community has much to gain. MMV's open innovation model of drug discovery relies on sharing the risk, cost and effort amongst a select research community, helping to catalyze research and allowing key partners to potentially generate intellectual property and file a patent. This early knowledge sharing not only forms a strong basis for the identification of exciting compounds but also for future partnerships and growth. Canada's support of PDPs such as MMV would significantly contribute to and strengthen the storehouse of Canadian science and R&D.

The federal government should harness the use of alternative funding mechanisms, such as MMV, to improve the efficiency of its development assistance resources, foster research and innovation, and catalyze additional resources from the global business sector, all of which could support national economic growth.

A commitment of resources aimed at supporting R&D for new health technologies, linked directly to Canada's newly increased contribution to the Global Fund, is likely to resonate strongly with Canada's NGO sector and other stakeholders. Umbrella organizations such as the Interagency Coalition on AIDS and Development, representing some 100 services organizations, NGOs, and educational institutions from across Canada, strongly supported Canada's increased Global Fund pledge and would likely similarly support funding for related R&D.

Similarly, such a commitment would be viewed as another step in advancing Canada's internationally recognized role in supporting evidence-based women and child health policy, especially given the disproportionate impact of malaria on this vulnerable population. MMV has already been warmly welcomed into the Canadian Partnership for Women and Children's Health and this commitment would further leverage Canada's expertise and global reputation in humanitarian work, research and innovation.

Finally, it will help to shore up the pipeline of treatments that are available to the Global Fund in future to help combat anti-microbial resistance to HIV, TB and malaria medicines.

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MMR, Aeras Global TB Vaccine Foundation, Drugs for Neglected Diseases Initiative, Foundation for Innovative New Diagnostics, International AIDS Vaccine Initiative, Innovative Vector Control Consortium, International Vaccine Initiative, Meningitis Vaccine Project, TB Alliance, and Global Health Innovation Fund.

We would therefore respectfully recommend that Canada allocate an equivalent minimum of 5 per cent of its Global Fund pledge towards R&D to advance the fight against the three diseases which would generate over \$4 million in research funding per year, per disease; at current resourcing levels, a \$4 million annual pledge would likely make Canada one of the top five donors to MMV.

Conclusion

Hosting the Global Fund's Replenishment Conference confirmed Canada's commitment to being at the centre of global plans to fight and ultimately end the epidemics of AIDS, TB and malaria. Canada now needs to underpin its commitment to the Global Fund by ensuring that upstream treatments for disease are discovered and delivered to those most in need. A decision to provide funding to support R&D to advance the global fight against AIDS, tuberculosis and malaria should be positioned by the government as part of an explicit virtuous cycle of funding and growth in the repository of Canadian research skills.

The increased pledge to the Global Fund, and hosting the 2016 Replenishment Conference, embodied Canada's determination to continue funding programs that are reaching those in need with proven healthcare interventions. Shoring up that investment by allocating funding towards R&D would signal a new, reinforced move by Canada to play a role in securing the core technologies upon which health service delivery programmes of the future will be built. Such technologies can be used for research into any disease and thus be of benefit to Canada and the world.