

**The Case of Ivermectin:
Lessons Learned and Implications for Improving Access to
Care and Treatment in Developing Countries**

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On October 21, 1987, Merck & Co., Inc., announced plans to donate MECTIZAN (ivermectin), a new medicine designed to combat onchocerciasis (“river blindness”), for as long as it might be needed. Merck took this action, working in collaboration with international experts in parasitology, the World Health Organization, and other agencies to reach those affected by the illness. This unusual decision came twelve years after the discovery of ivermectin by Merck scientists and nearly seven years after the first human clinical trials in Dakar, Senegal. Merck chairman Raymond V. Gilmartin has since reaffirmed the company’s commitment to donate “as much MECTIZAN as necessary, for as long as necessary, to treat river blindness and to help bring the disease under control as a public health problem.”

River blindness is caused by parasitic worms that breed in fast-flowing rivers. The disease is transmitted to humans by the bite of infected blackflies. The adult worms produce millions of offspring (or microfilariae) that move throughout the body, causing intense itching, skin lesions, sight impairment and, eventually, blindness. In addition to the disfigurement, debilitation and blindness caused by the disease, it leads to social and economic disruption in the lives of communities forced to abandon fertile plains near rivers.

Today, some 120 million people are still at risk of contracting onchocerciasis (with some 18 million already infected, and 1-2 million people already visually impaired or blinded) in the 35 countries where the disease is endemic. Through the continuing collaboration of an international, multi-sectoral coalition including the WHO, the World Bank, UNICEF, the MECTIZAN Expert Committee, and dozens of national Ministries of Health, representatives of the international donor community, more than thirty non-governmental development organizations, and local community health workers, there is hope that onchocerciasis can be eliminated as a major public health problem and socioeconomic development constraint within the next decade.

The Merck MECTIZAN Donation Program (MDP) is now the largest ongoing donation program of its kind. There are active treatment programs in 33 of 35 countries in Sub-Saharan Africa, Latin America, and Yemen in the Middle East where onchocerciasis is endemic. To date, more than half a billion MECTIZAN tablets have been donated and shipped since the inception of the Program. An estimated 25 million individuals are treated annually, with the 200 millionth treatment slated to take place later this year. The donation of MECTIZAN for lymphatic filariasis (in African countries where

lymphatic filariasis and onchocerciasis are co-endemic) was launched in 2000 in Ghana, Togo and Tanzania. The Program was extended to four additional countries this year – Burkina Faso, Uganda, Cote d’Ivoire, and Benin.

Challenges and obstacles

At the start of the MECTIZAN experience, there were significant challenges to expanding access to this safe and effective treatment for onchocerciasis. Although treatment requires only one annual dose, easily administered, governments were not convinced initially of the feasibility of providing treatment, due to the lack of ancillary resources needed to distribute the medicine to patients in need (often in remote rural areas). There were competing health priorities, and no ready way to sort through the value of different initiatives. There were relatively poorly developed community health infrastructures in many of the countries hardest hit by onchocerciasis. Treatment programs faced both distribution and logistical challenges (including the technical issues of drug importation regulations and customs duties). Finally, since onchocerciasis strikes populations in remote areas in some of the poorest countries in the world, the political and civil unrest in some of these countries made it even more difficult to try to make the arrangements necessary to place free MECTIZAN in the hands of people infected with, or at risk of contracting, river blindness.

Lessons learned

What lessons have we learned from the MECTIZAN experience? What has it taught us about how to mobilize resources in successful public/private partnerships to address significant health problems – and to do so in a way that significantly reduces disease burden over the long term?

In one sense, of course, MECTIZAN is unique -- effective treatment requires only one annual dose, easily administered, with no major side effects. But it nonetheless provides an instructive case study in the interrelations of scientific and clinical research, corporate social responsibility, and the challenges of health and development. Some of the critical success factors from this experience include:

- the need to focus scientific and clinical research resources on feasible targets for clearly important health priorities;
- the importance of partnerships among public sector and private sector organizations (including non-governmental development organizations) to control a dreadful disease, informed by the needs of the people whose lives are directly affected; and
- the essential role of distribution mechanisms and healthcare infrastructure in ensuring that medicines like MECTIZAN reach those who need them

Partnerships

The value of partnerships in advancing the cause of global health cannot be overstated. The complexity of the issues we face, the entrenched nature of the diseases we fight, and the fragility of the healthcare infrastructures we seek to build are all beyond the ability of any single organization or country alone to address. It is critical that the public and private sectors work together in a way that enables the people who are most directly affected to determine their own needs and priorities. Partnerships work best when based on clear objectives, trust, complementary expertise, and mutual benefits. And the continuing need for coordination, communication, and commitment from all stakeholders in the process is crucial to success.

Infrastructure

Merck's responsibility in meeting global health needs goes beyond discovering and developing a medicine like ivermectin, and beyond merely making charitable contributions. In over a decade of experience, we have learned that simply removing cost as a barrier (by providing medicine free of charge) is not enough in itself to ensure that the medicine gets to the people who need it most.

Sustainability

MECTIZAN also shows that for a donation program to succeed in a significant way, commitments to ensure sustainability are as critical as promises to supply product. The MDP example is one instance of how drug donation programs can be sustainable. Merck has made a commitment to provide MECTIZAN for river blindness wherever necessary, for as long as necessary. For organizations that supply MECTIZAN via community health programs, the MECTIZAN Expert Committee requires a minimum five-year commitment before agreeing to supply the medicine. And the strategy of CDTI (community-directed treatment with ivermectin) has been employed to ensure sustainability by having MECTIZAN delivered to patients by village health workers as part of regular healthcare delivery – in fact, a remarkable 34,440 communities in affected regions are now planning and managing MECTIZAN distribution.

The MDP case also suggests that donation programs should, where possible, be integrated into a country's healthcare system. For example, onchocerciasis control efforts in endemic countries have been supported by the training of local (country and community-level) healthcare workers in the distribution, administration and monitoring of MECTIZAN treatment. Subsequently, these enhanced skills have enabled healthcare personnel to apply their knowledge to other initiatives that support a country's healthcare objectives. In this fashion, treatment of lymphatic filariasis can benefit from the existing delivery structure for river blindness where the two diseases co-exist. The involvement of the political and health structures of affected countries, together with the communities directly affected by the disease, has proven essential to routine distribution activities, long-term program sustainability and overall success in diminishing disease burden.

Doing well is a precondition to doing good: an enabling policy environment (including, for instance, adequate TRIPS-compliant intellectual property protection standards) is a prerequisite for a company to have the wherewithal to mount a major philanthropic program like The Merck MECTIZAN Donation Program.

Health impact, capacity building, and implications for future access programs

The case of MECTIZAN clearly demonstrates the power and possibilities in strong, transparent, and creative public/private partnerships to help address the enormous public health challenges facing developing countries today. Since the inception of the MDP, some 16 million children have been spared the risk of infection in 11 countries in West Africa due to a spraying program combined with MECTIZAN treatment. The World Bank reports that 25 million hectares of arable land have been recovered – enough to feed 17 million people. More than 600,000 cases of blindness have been prevented.

The cooperative nature of the program has helped to strengthen the primary healthcare system in many countries where MECTIZAN is delivered: indeed, the delivery infrastructure and treatment strategy have resulted in the delivery of other health services (e.g., vitamin A in the Central African Republic) and diagnosis of other conditions (e.g., cataracts). One might plausibly argue that the MDP is not simply a drug donation program, but rather a public health initiative carried out by a multi-sectoral public/private partnership. The initial decision to donate MECTIZAN served as a catalyst for a much broader -- and effective -- health intervention.

Donation programs have never been promoted as the solution to the global access crisis, nor should they be. But they offer one mechanism for providing access to care and treatment, which should be evaluated on a case-by-case basis (depending on the disease, medication, available infrastructure, etc.). While donation programs may not be perfect, they should be encouraged where appropriate. To a certain extent, the MDP has served as a model for new donation programs like the International Trachoma Initiative (undertaken by Pfizer in collaboration with the Edna McConnell Clark Foundation and the WHO) and GlaxoSmithKline's partnership with the WHO to eliminate lymphatic filariasis from 73 nations.

The Merck MECTIZAN Donation Program – which has helped millions of people in the developing world – is an instructive case, reminding us that even when medicines are free, questions of infrastructure, transparency, distribution, logistics, partnership, and sustainability structure the prospects for long-term health benefits. These lessons are suggestive in considering approaches to other medical conditions and other programs of care and treatment in the developing world. While simple solutions won't work, the MECTIZAN case, by showing what can be achieved, is a cause for optimism.

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