

ANNUAL HIGHLIGHTS 2012

The Accomplishments of the
Mectizan Donation Program
in its 25TH Year



Message from the Director Dr. Adrian Hopkins

It's not often we hear about international health programs that go on for 25 years; so it's remarkable that after 25 years, the Mectizan Donation Program is still scaling up. We're also discussing the beginning of the end. Where we once focused on controlling the disease indefinitely, we now consider eliminating the disease altogether. The disease has been virtually eliminated in the Americas; with new strategies and renewed commitments, we hope to one day say the same for Africa and Yemen.

The impact the donation of Mectizan has had on individuals is also remarkable. I'd like to mention two in particular. One was brought to my hospital decades ago almost blind, only able to distinguish light and dark. I'd first met him as a ferryman when he would paddle me across a Congo River tributary in a dugout canoe when I was traveling by motorbike. One day the canoe broke and we had to use a smaller dugout, which required careful balancing of the motorbike in the canoe in a stream full of crocodiles, but that's another story!

The ferryman was brought in after being treated for river blindness with a drug called diethylcarbamazine (DEC). DEC killed the parasites that cause river blindness, but it caused inflammation in the eye and destroyed his vision. He never paddled me across that river again. Back then, DEC was the only option to treat patients with river blindness, but it caused such damage that it was better to let people slowly go blind than risk the sudden blindness following treatment with DEC.

Twenty four years ago I had another patient in the Congo. I examined his eyes with a slit lamp and I could see the microfilaria, or juvenile worms, swimming in the liquid in his eye. We had just received a new drug called Mectizan. We treated him and watched his eyes gradually get better. The microfilaria slowly disappeared and his vision was saved. That has been the real impact of this remarkable disease intervention. These were just two individuals. Today, we treat millions.

Some of you may have seen the video that we produced for the 25th anniversary of The Mectizan Donation Program. Making that video brought to light a third story about the impact Mectizan has had on communities.

We were interviewing a blind man in a village in the northwestern part of Central African Republic (CAR). He told me that, though he had already lost his vision to river blindness, 20 years before he attended an eye clinic I conducted in Bossangoa, CAR. His blindness was too far advanced to be reversed by treatment with Mectizan, but he took the drug anyway to relieve the itching caused by the disease. Because of his blindness, he was abandoned by his family and he

moved to a neighboring village to live with his uncle. During this film trip, we found him at his uncle's home and he reminded me of his participation in the eye clinic all those years ago. He was still very grateful for Mectizan and commented, "since you started Mectizan distribution all those years ago we don't have any more new blind people in this village." That's the difference the drug has made in just one generation.

In 2013 we will mark 15 years since GSK and Merck committed to donate albendazole and Mectizan respectively to eliminate lymphatic filariasis (LF) in co-endemic countries in Africa and in Yemen. Great progress has been made.

Treatment has been stopped in some countries And they are now in the post treatment surveillance phase. Millions of children will now grow up without the risk of the debilitating and hideous limb swelling caused by LF infection.

We celebrated success with our partners in 2012 - but 2013 is a new year and we still have a steep road to climb. The newly developed strategic vision of the Mectizan Donation Program states clearly that elimination is the goal - by 2020 for LF and 2025 for onchocerciasis. The closer we get to the end point, the more difficult the work will become. MDP is moving forward with a new strategic plan and we look forward to working more effectively with our partners to achieve these ambitious goals.



2012 River Blindness (Onchocerciasis) Achievements

In 2012, MDP approved a total 116,487,375* Mectizan treatments for Africa and Yemen. Of this total, 34,584,370 treatments were approved for both river blindness and lymphatic filariasis (LF) where the two diseases are co-endemic.

The LF elimination programs in Guinea and Liberia submitted joint applications for Mectizan and albendazole for the first time. The application from the Democratic Republic of the Congo included a request to treat river blindness in a new project, Ituri Sud, which was approved by the Mectizan Expert Committee.

From the inception of the program in 1987 to date, a cumulative total of 1,154,845,523 treatments have been approved for river blindness.

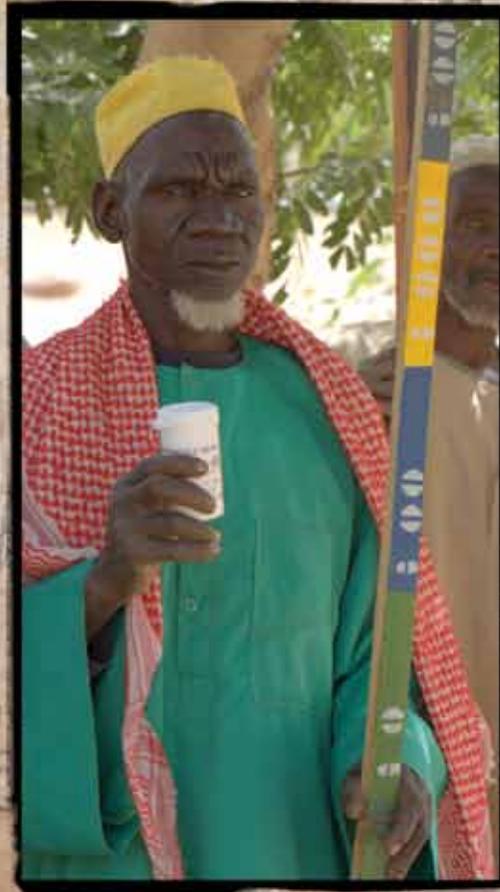
Stopping MDA and Post Treatment Surveillance (PTS)

Sudan: Treatment for river blindness was stopped in Abu Hamad and post treatment surveillance is now underway. The Mectizan Donation Program congratulates the Sudan Federal Ministry of Health and NGO partner The Carter Center for achieving elimination of transmission in this region.

Uganda: MDP also congratulates the Ministry of Health in Uganda and The Carter Center for stopping Mectizan treatment for onchocerciasis in three foci: Elgon, Itwara, and Wadelai. In these areas, Uganda implemented an elimination strategy and twice yearly Mectizan treatment was combined with vector control, which resulted in the successful elimination of transmission of river blindness in those foci.

Americas: For the first time since the Program began, no Mectizan was shipped to any of the six endemic countries in the Americas. Mass treatment is still ongoing in Brazil and Venezuela and it is expected that those foci will stop treatment by 2015.

*In 2011, 140 million treatments were approved. Of these, approximately 18 million treatments were pre-approved for distribution in 2012, hence the reduction in the number of treatments approved for 2012.



2012 Lymphatic Filariasis Achievements

By the end of 2012, 22 of the 28 African countries and Yemen were working toward LF elimination (LFE) using albendazole and Mectizan for mass drug administration (MDA) to interrupt the transmission of lymphatic filariasis (LF). Since the beginning of the Program in 2000, more than 665 million treatments have been approved. As MDA for LF continues to scale up, the number of treatments approved continues to increase every year as new countries launch LF elimination programs and others expand into new implementation units (IUs).

In 2012, 150.0 million treatments were approved for LFE. Among the applications approved, one new application was approved to start a countrywide LF programme in Sierra Leone using the onchocerciasis control program as a platform. Applications were approved for the continuation of treatment in Benin, Burkina Faso, Central African Republic, Ghana, Guinea Bissau, Malawi, Nigeria, Senegal, and Sierra Leone. Applications were also approved for program expansion in Cameroon, Cote d'Ivoire, Ethiopia, Mozambique, Nigeria, Senegal, and Tanzania.

Stopping MDA and Post Treatment Surveillance (PTS)

- Burkina Faso:** Treatment stopped in 6 IUs
Total population: 1,500,768
- Nigeria:** Last MDA conducted in 2012 in Plateau and Nasarawa states (30 IUs) Total population: 5.5 million
- Ghana:** Treatment stopped in 4 IUs:
Total population: 627,297
- Tanzania:** Treatment stopped in 1 IU Total population: 243,885; PTS continues in Zanzibar
- Togo:** PTS activities continue; second transmission assessment survey (TAS) conducted
- Yemen:** PTS activities continue

Geneva

Coinciding with the World Health Assembly, MDP hosted a celebratory event in Geneva, which was well-attended by partners including the WHO AFRO Director General, ministers of health from Togo and Southern Sudan and other country representatives, the PAHO Director General, two former MDP directors, and representatives from GSK and Merck.

The event opened with a welcome from Dr. Henrik Secher, MSD's Managing Director for Africa. Dr. Secher was followed by remarks by Sudan's Minister of Health, the Honorable Mr. Bahar Idris Abu Garda. Mr. Garda commented "The elimination of the disease in the Abu Hamad area was not even a dream, which makes the achievement a good lesson to be followed in other parts of Sudan and even in other African countries." Mr. Abu-Garda was followed by Togo's Minister of Health, Prof. Kondi Charles Agba. Togo has been successful in reducing levels of LF parasites in humans to a point where treatment can be stopped.

Brazil's Vice-Minister of Health Surveillance, Dr. Jarbas Barbosa, and the PAHO Director General, Dr. Mirta Roses Periago then made remarks on the successful elimination of onchocerciasis in the Americas. The program closed with remarks from the World Bank's Don Bundy who spoke on the value of partnerships and the positive impact of the collaboration between the Mectizan Donation Program, the World Health Organization, and the African Program for Onchocerciasis Control.



Togo Minister of Health Prof. Charles Kondi Agba



L-R Dr. Allen Foster, Dr. Luis Sambo, Mr. Jon Snow, Dr. Mauricio Sauerbrey, Dr. Ariel Pablos Mendez



L-R Dr. Bill Foege, Dr. Roy Vagelos

CELEBRATING 25 YEARS OF PARTNERSHIP

2012 marked 25 years of Merck's donation of Mectizan. To celebrate, Merck and the Mectizan Donation Program brought partners together in Geneva, London, and Atlanta to recognize the remarkable achievements that have been made and to restate the commitment from control of river blindness to elimination. MDP looks forward to working with partners on future achievements to eliminate both river blindness and lymphatic filariasis.

London

MDP celebrated in London with UK and Europe-based partners with a panel discussion on "Eliminating Disease in the 21st Century." Mr. Kenneth Frazier, Merck Chairman and CEO welcomed the audience. Mr. Frazier commented "... twenty-five years ago, many in this room dared to imagine a different world – a world free from the scourge of river blindness, one where a new generation in Africa, Latin America and elsewhere might be liberated from this tragic birthright. Where people could reach their full potential as human beings because they had the gift of sight for their entire lives."

Dr. Caroline Harper, OBE, Sightsaver's Chief Executive, delivered the keynote address. Dr. Harper gave a rousing speech on why we must remain committed and strengthen advocacy for river blindness elimination. The keynote speech was followed by a fascinating panel discussion featuring: CBM President and former MEC Chair, Dr. Allen Foster, Onchocerciasis Elimination Program for the Americas Director Dr. Mauricio Sauerbrey, WHO AFRO Regional Director General, Dr. Luis Sambo, and Dr. Ariel Pablos-Méndez, USAID Assistant Director for Global Health. The evening was moderated by the UK's Channel 4 presenter Mr. Jon Snow.

Partnership and Progress

Atlanta

The Mectizan Donation Program celebrated with an event at The Carter Center that featured a lively panel discussion with former MEC Chair and world renowned global health expert, Dr. Bill Foege, former MERCK CEO, Dr. Roy Vagelos, and former President Jimmy Carter. The event was moderated by Dr. Mark Rosenberg, President of the Task Force for Global Health. A video of the event will soon be available on www.mectizan.org. These three visionaries all played very important roles in the early days of the Mectizan Donation Program and over the course of the evening recalled some humorous memories as well as some of the struggles they encountered during the early years. Despite the struggles, the effort was well worth it. Dr. Foege recalled "River blindness is a terrible thing to watch. Itching is the first thing they know in the morning and the last thing they know at night...After people took Mectizan, some had the first itch-free day that they could ever remember." Following the event, Dr. Foege published an opinion editorial about the Program in the Washington Post, which can be read here: <http://www.mectizan.org/news/washington-post-op-ed-on-mdps-25-years-by-bill-foege>.



Dr. Bill Foege, President Jimmy Carter, Dr. Mark Rosenberg

Merck Mectizan Award

The Mectizan Donation Program congratulates the 2011 and 2012 recipients of the Merck Mectizan Award.

The 2011 Award was presented during the anniversary celebration in Geneva in May to Dr. Björn Thylefors for his contributions to the control and elimination of onchocerciasis and lymphatic filariasis. Some of his many achievements include:

- ⊗ Advocating for the prevention of blindness in the developing world by contributing to the Vision 2020 plan for the elimination of avoidable blindness.
- ⊗ Conducting groundbreaking research on eye diseases associated with river blindness infection.
- ⊗ Forming strong partnerships with WHO, Ministries of Health and nongovernmental development organizations (NGDOs) that are still effective more than 20 years later. Dr. Thylefors' work as liaison between WHO and the NGDOs led to the formation of the NGDO Coordination Group for Ivermectin Distribution in 1991, a critical component of the global onchocerciasis partnership structure.

During his acceptance speech, Dr. Thylefors noted



Dr. Björn Thylefors receives Merck Mectizan Award from Ms. Brenda Colatrella

"The magnitude of the distribution of Mectizan in endemic areas, with presently more than 100 million doses approved each year, represents an achievement simply unimaginable 25 years ago." This statement was an appropriate emphasis on the achievements made by partners over the first 25 years of the donation of Mectizan.

The 2012 award was presented to Dr. Mauricio Sauerbrey by Mr. Kenneth Frazier for his outstanding dedication to the elimination of onchocerciasis from the Americas. Dr. Sauerbrey's achievements include:

- ⊗ Leading the effort to achieve at least 85% or higher therapeutic coverage in the six river blindness endemic countries in the Americas leading to the successful interruption of transmission in Colombia, Ecuador, Guatemala, and Mexico.
- ⊗ Contributing to the development of new strategies for river blindness elimination based on his innovative decentralized approach to reducing malaria in El Salvador.
- ⊗ Demonstrating leadership and diplomacy in advocating for a disease that is a low priority for ministries of health.



Dr. Mauricio Sauerbrey (L) receives Merck Mectizan Award from Mr. Ken Frazier

Mectizan Expert Committee (MEC) Highlights

The Spring and Fall MEC meeting were held in May in Geneva, coinciding with the World Health Assembly, and in October in London.

As the Program has evolved, the MEC's role has changed. When the program began, the MEC's primary role was to review and approve new applications for Mectizan for onchocerciasis control, and later, Mectizan and albendazole for lymphatic filariasis (LF) elimination in co-endemic countries in Africa. Now that the program has matured, new applications are rare and the issues around onchocerciasis and LF elimination are increasingly complex.

The MEC now provides a wide range of technical expertise with an emphasis on ensuring that MDP operations are effective and that the drugs are used effectively. In 2012, the MEC was also engaged in helping develop MDP's 5-year Strategic Plan. The final draft of the plan will be presented to the MEC during the Spring 2013 meeting.

In 2012, some of the issues discussed by the MEC included:

Treatment for onchocerciasis in a new project in Ituri Sud, Democratic Republic of the Congo (DRC) and the need to ensure that Mectizan is distributed safely there as this area is near an area endemic for loiasis, a disease that complicates the use of Mectizan due to adverse reactions. The MEC recommended ensuring that a new technical advisor (TA) be recruited to ensure that the MEC/APOC Technical Consultative Committee guidelines are followed in these areas and that adequate monitoring and reporting are in place.

A request from Ethiopia for twice yearly treatment was reviewed. Noting that the implementation strategy needed to be more well-defined, the MEC requested clarification on the strategy from the Ministry of Health and other partners including the African Program for Onchocerciasis Control (APOC).

Nodding disease is a condition observed in some onchocerciasis endemic areas. Following a presentation of CDC's findings on nodding disease, which noted that the causal relationship with onchocerciasis is yet to be established and the use of Mectizan has little direct effect on patients, the MEC did approve the use of Mectizan for the treatment of onchocerciasis and lymphatic filariasis in patients suffering from nodding disease but only in areas where MDA is ongoing.

A new application from Guinea Conakry for LF elimination was approved pending the results of base line surveys for LF prevalence given that treatment of onchocerciasis with Mectizan has been ongoing for a number of years in the region.



In areas where it is suspected that transmission for LF has been interrupted, transmission surveys should be conducted before treatment for LF elimination is stopped.

The MEC approved the continued use of Mectizan for onchocerciasis treatment in Togo but requested that the results of the joint epidemiological evaluation for onchocerciasis and LF be shared before Mectizan is approved for further rounds of treatment. Similarly, in Guinea Bissau, prior to starting MDA for LF the MEC recommends further baseline studies in sentinel sites that were previously treated with Mectizan for onchocerciasis.

LF program managers working in *Loa* endemic areas should be informed of the possibility that adverse events are possible in areas already under treatment for onchocerciasis when previously noncompliant patients present for LF treatment. The MEC/APOC Technical Consultative Committee guidelines should be followed in these areas.

The training manual for family care of comatose patients in DRC and Cameroon should be finalized and the manual should



be field tested during the next treatment rounds. Multi-stage testing should be conducted and translation of the manual into local languages to ensure it is understood by health care workers and families at all levels of literacy.

To accurately forecast drug needs for the future, the MEC agreed that there is an urgent need to:

- ☉ Define treatment strategies in hypo-endemic areas of onchocerciasis
- ☉ Define the populations that would be added to existing treatment areas
- ☉ Establish policies for twice-yearly treatment with Mectizan and estimate the populations requiring increased frequency of treatment
- ☉ Complete mapping of LF in all co-endemic areas as quickly as possible
- ☉ Map overlapping areas for LF and onchocerciasis

The MEC supported the increased efforts in the Amazon region of the Americas to eliminate the disease using a strategy of quarterly treatment with Mectizan and the use of doxycycline where appropriate. The MEC encouraged further strengthening cross border efforts between Venezuela and Brazil.

There is an enormous amount of scientific work being undertaken in Yaounde by the Cameroon Filariasis

Research Center (CRFIL). The MEC encouraged the scientific sub-committee for the Center to keep the program focused on important work related to the control of filarial diseases.

WHO AFRO's increased coordination of NTD control was discussed by the MEC and it was noted that the coordination of technical and programmatic issues among partners needs to be better defined.

The MEC appreciated the necessity to investigate cases of sub-optimal response to Mectizan and the potential for resistance. It was decided that the Spring 2012 MEC meeting in Accra, Ghana would be preceded by a stakeholders meeting to discuss Mectizan efficacy and the need to be proactive in preparing program managers for potential resistance and to define research needs.

The MEC was concerned with the poor coverage of MDA for LF in many LGAs in Nigeria and therefore only approved continuing treatment for LF at the current levels in Nigeria (approx 29 million treatments). Further scaling up was deferred pending improved coverage in non-onchocerciasis areas. The MEC proposed a joint mission to Nigeria with AFRO and APOC to discuss the challenges.





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Through the Mectizan Donation Program, Merck donates Mectizan for the elimination of onchocerciasis as a public health problem in Africa, Latin America, and Yemen. For the elimination of lymphatic filariasis in Africa and Yemen where onchocerciasis is co-endemic, Mectizan is co-administered with albendazole, which is donated by GlaxoSmithKline.

Mectizan is not approved for use in the United States.

