Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination
Progress—River Blindness

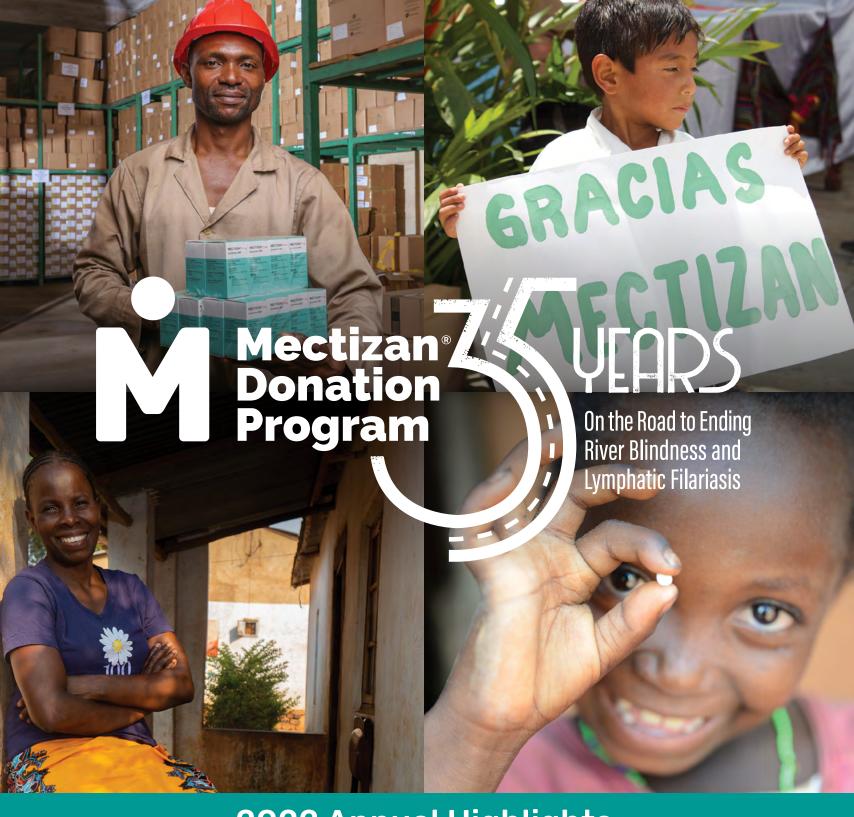
2022 Elimination
Progress—
Lymphatic Filariasis

2022 News

MDP at 35: A Look Back







2022 Annual Highlights

Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination Progress—River Blindness

2022 Elimination
Progress—
Lymphatic Filariasis

2022 News

MDP at 35: A Look Back









35 YEARS OF MECTIZAN

Message from Dr. Yao Sodahlon, Director

In 2022, we celebrated
35 years of Mectizan®. It is
truly amazing to reflect on
how far we've come since
Merck & Co., Inc.* announced the
donation in October 1987.

The Mectizan Donation Program was established to combat one neglected tropical disease—river blindness (onchocerciasis). The successful control of river blindness through mass drug administration led in 1998 to an expansion of the program to include the donation of Mectizan for another NTD, lymphatic filariasis (LF), in African countries and Yemen where the two diseases co-exist. For the elimination of LF, Mectizan is co-administered with albendazole, donated by GSK. In 2017, Merck announced further expansion to include countries eligible for "triple therapy" (Mectizan [ivermectin] + DEC + albendazole, also known as IDA) to accelerate LF elimination.

A year of progress

Progress was reported for both diseases in 2022. Following the required evaluations for river blindness elimination, 45.7 million people in eight African countries no longer need treatment.

Niger is well on its way to becoming the first country in Africa to submit its dossier to the World Health Organization (WHO) to verify that river blindness transmission has been eliminated. An exciting development!

Senegal stopped treatment for onchocerciasis in all endemic communities and will begin the 3-year post-

treatment surveillance phase to ensure transmission has been interrupted.

Nigeria has made extraordinary progress toward elimination of transmission of river blindness. Treatment was stopped in 2022 in four additional states—Abia, Anambra, Enugu, and Imo—bringing the number of states that have stopped treatment in Nigeria to 10. This important milestone covers nearly 37 million people who no longer need Mectizan treatment for river blindness in 131 local government areas (LGAs).

We applaud the countries, communities, and constellation of partners who are helping to make this happen.

The future of lymphatic filariasis elimination is also looking bright. The effort to eliminate LF in countries co-endemic with river blindness began in 1998. We have seen great progress. In 2022, a celebration was held in Malawi to congratulate the country on achieving elimination of LF in 2020 and to present the second GSK-MDP-Merck LF elimination award. The event was attended by dignitaries from the government of Malawi and by African LF program managers who were there for a progress review meeting co-sponsored by Global Alliance to Eliminate Lymphatic Filariasis (GAELF) and WHO. The opportunity to combine the events enabled program managers to witness that, despite the challenges, LF elimination is achievable.

For LF, 265 million people in 18 countries no longer need treatment with Mectizan and albendazole. This remarkable program downscaling is bringing us closer to the WHO 2030 NTD Road Map targets to stop treatment for LF worldwide by 2030.

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back







By the end of 2022, we reached two impressive milestones: the five billionth Mectizan treatment approved, and one billion Mectizan tablets shipped in a single year.

In 2022, nearly 378 million treatments were approved for river blindness and LF elimination—a modest increase from 2021 when 364 million treatments were approved. This includes 62 million treatments approved for the implementation of "triple therapy" in six countries. So far, Merck has shipped Mectizan to 21 countries and territories where river blindness is not endemic to facilitate the implementation of IDA to accelerate the elimination of LF.

By the end of 2022, we reached two impressive milestones:

- 1. The five billionth Mectizan treatment approved by the Mectizan Donation Program since the donation was announced in 1987; and
- 2. One billion Mectizan 3 mg tablets shipped by Merck in a single year to endemic countries. It is worth noting that the first billion tablets shipped took 17 years, from 1987 to 2004, with a dramatic increase following the addition of LF elimination to our mandate. For more details, see the progress reports starting on page 5.

Looking to the future

In 2023, we hope to see Niger verified by WHO for achieving the elimination of transmission of river blindness, and we look forward to celebrating the first country in Africa to achieve this important milestone.

We were delighted to participate in preliminary activities for the creation of the new Global Onchocerciasis Network for Elimination (GONE). GONE was established by WHO to empower countries and facilitate progress by strengthening collaboration among stakeholders toward the Road Map goals for river blindness elimination. GONE was officially launched on World NTD Day in January 2023. At the inaugural face-to-face meeting of the network in Fall 2023,

partners will agree on the goals for this new partnership, which aims to accelerate interventions to stamp out river blindness so that it is GONE forever.

In spring 2022, MDP and Merck announced a donation of \$500,000 to strengthen laboratory capacity to support river blindness elimination in Africa. The donation is managed in partnership with the WHO Collaborating Centre for Onchocerciasis Diagnostics at the College of Public Health, University of South Florida. Learn more at bit.ly/OnchoLabGrant.

Finally, I would like to thank our country partners who signed the new agreement with the Mectizan Donation Program to receive Mectizan for river blindness and LF elimination. The new 5-year agreement clarifies the conditions of the donation and the roles and responsibilities of the signatories. This new agreement will facilitate the supply process and ensure the responsible use of Merck's generous donation of Mectizan. We encourage the remaining countries to sign the new agreement, effective January 2023, so that they remain on track for eliminating both diseases.

On behalf of the MDP team and the Mectizan Expert Committee, I am committed to doing our part to ensure momentum is sustained toward eliminating these two disabling diseases by working with WHO and partners to move countries towards the 2030 NTD Road Map goals. Together we will #StampOutOncho and #EliminateLF!

Dr. Yao Sodahlon, Director Mectizan Donation Program

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*Merck & Co., Inc. is known as MSD outside the United States and Canada.



Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination **Progress**— **Lymphatic Filariasis**

> > **2022 News**

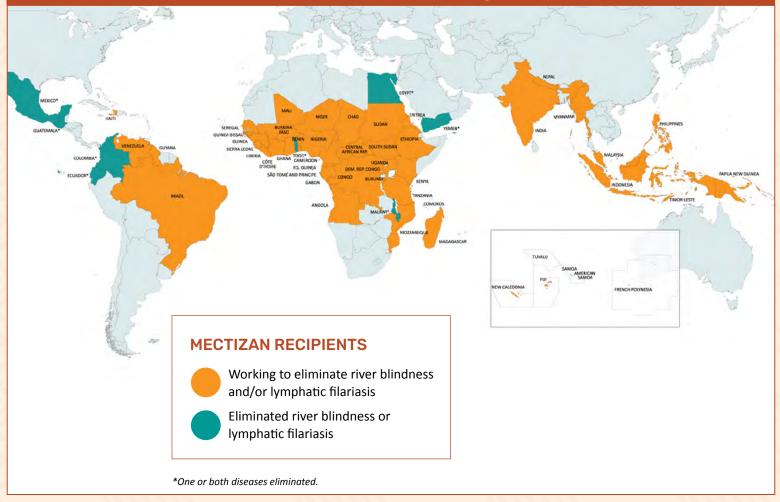
MDP at 35: A Look Back





THE GLOBAL REACH OF THE MECTIZAN DONATION PROGRAM

Since 1987, Mectizan has been donated for mass administration to a total of 58 countries and territories. For details, see our website: mectizan.org/where-we-work/





Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination Progress—River Blindness

2022 Elimination
Progress—
Lymphatic Filariasis

2022 News

MDP at 35: A Look Back

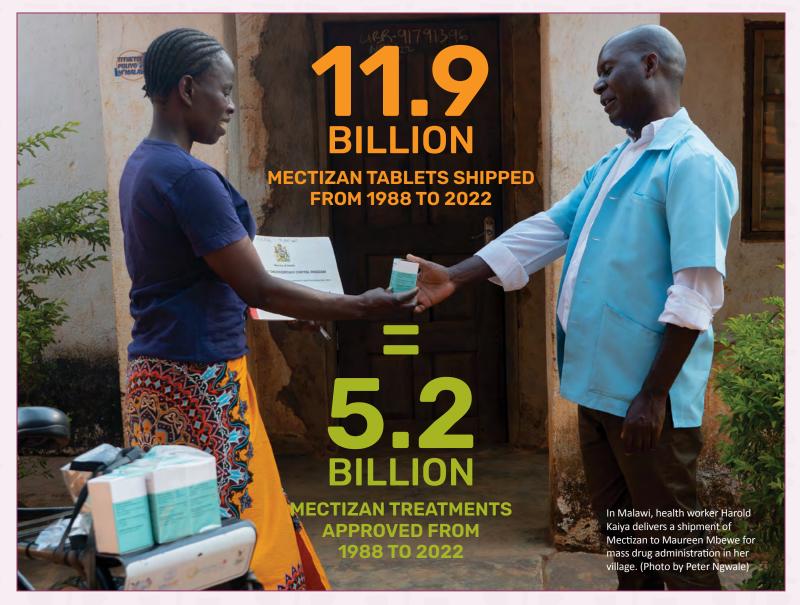






Astonishing numbers of people continue to come off treatment for river blindness and LF—a strong indicator of progress toward the elimination of these diseases.

2022 ELIMINATION PROGRESS



Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> **2022 Elimination Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination **Progress**— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back

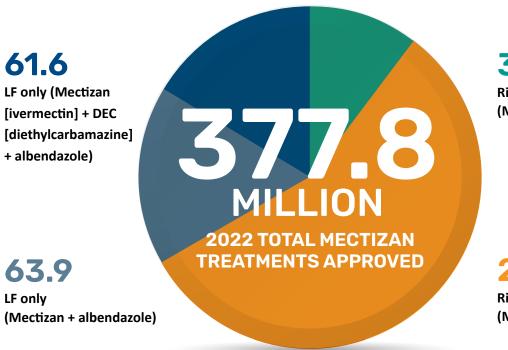


PROGRESS TOWARD RIVER BLINDNESS AND LYMPHATIC FILARIASIS ELIMINATION

2022 Elimination Progress-Overview

In 2022, the Mectizan Donation Program approved 377.8 million Mectizan treatments for mass drug administration (MDA) to eliminate river blindness (onchocerciasis) and lymphatic filariasis (LF) in 31 countries and territories around the world.

Figure 1: Total treatments approved 2022 (in millions)



39.2

River blindness + LF (Mectizan + albendazole)

213.1

River blindness only (Mectizan)



We are happy to report that the Mectizan supply chain has returned to its previous level of efficiency following the epidemic phase of COVID-19.

CONTENTS

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> **2022 Elimination Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress-**Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back





2022 Elimination Progress-Overview

An estimated 46 million people no longer need treatment for river blindness. For LF, 265 million people no longer need treatment. It is remarkable to see this progress each year as countries downscale the number of people who need treatment.

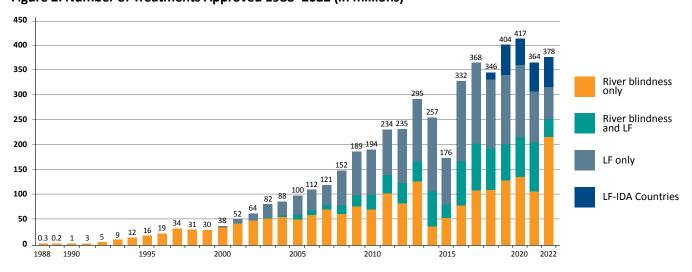
The expansion of the donation in 1998 and again in 2017 led to increases in the number of Mectizan tablets shipped by Merck year after year, reaching over 1 billion tablets in 2022. Over the past two years, however, circumstances such as the global COVID-19 pandemic led to a decrease in the supply. Due to COVID, some countries missed the annual mass drug administration (MDA), resulting in leftover inventory. Further, the supply chain challenges that impacted shipments of goods worldwide resulted in shipping delays that impacted around 30% of the tablets requested during those years. We are happy to report that the Mectizan supply chain has returned to its previous level of efficiency as operations have returned to normal with our shipping partners and partner countries.

Since the inception of the donation program in 1987, nearly 12 billion Mectizan 3 mg tablets have been supplied by Merck to support river blindness and lymphatic filariasis elimination for the 5.2 billion treatments approved by the Mectizan Donation Program and Mectizan Expert Committee.



Community Drug Distributor Maureen Mbewe prepares to distribute Mectizan in her community in southern Malawi. (Photo by Peter Ngwale)

Figure 2: Number of Treatments Approved 1988–2022 (in millions)





ONCHOCERCIASIS ELIMINATION IN 2022

CONTENTS

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination **Progress**— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back





2022 Elimination Progress-River Blindness (Onchocerciasis)

In 2022, 252.3 million treatments were approved for elimination of river blindness in 22 African countries, plus Yemen (Figure 3).

Downscaling: as of the end of 2022, over 45 million people in 13 countries in Africa and the Americas were living in areas where transmission is suspected to have been interrupted or eliminated; therefore treatment with Mectizan is no longer needed. Of these, 14.4 million people remain under treatment with Mectizan and albendazole for the elimination of LF. Post-treatment surveillance for river blindness will begin in these communities when they pass the transmission assessment surveys required to determine when treatment for LF can be stopped.

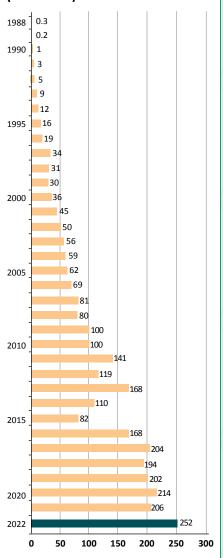
Table 1 shows the population for whom treatment for onchocerciasis has been stopped since transmission is suspected to have been either interrupted or eliminated (as of December 2022).

Table 1: Mectizan Treatment Stopped for Onchocerciasis

table 1. Weetizah freatment stopped for Offenoerelasis							
Country	Onchocerciasis foci no longer needing treatment	Total onchocerciasis foci/districts	Population in onchocerciasis foci where treatment has stopped	Population in onchocerciasis foci where treatment has stopped but still under treatment for LF			
Colombia*	1	1	1,515				
Ecuador*	1	1	30,015				
Equatorial Guinea	4	4	269,290				
Ethiopia	26	268	2,614,600	83,426			
Guatemala*	4	4	286,521				
Mali	2	22	951,891	0			
Mexico*	3	3	227,118				
Nigeria	131	482	36,593,045	14,203,363			
Senegal	8	8	594,843	140,995			
Sudan*	2	4	356,043				
Togo	3	36	521,025				
Uganda*	15	17	3,171,949	0			
Venezuela	2	3	122,128				
Total	202	853	45,739,982	14,427,784			

^{*} In the Americas, Sudan, and Uganda, the geographical unit is a focus rather than a district.

Figure 3: Treatments Approved for River Blindness, 1988-2022 (in millions)



Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress— **Lymphatic Filariasis**

> > **2022 News**

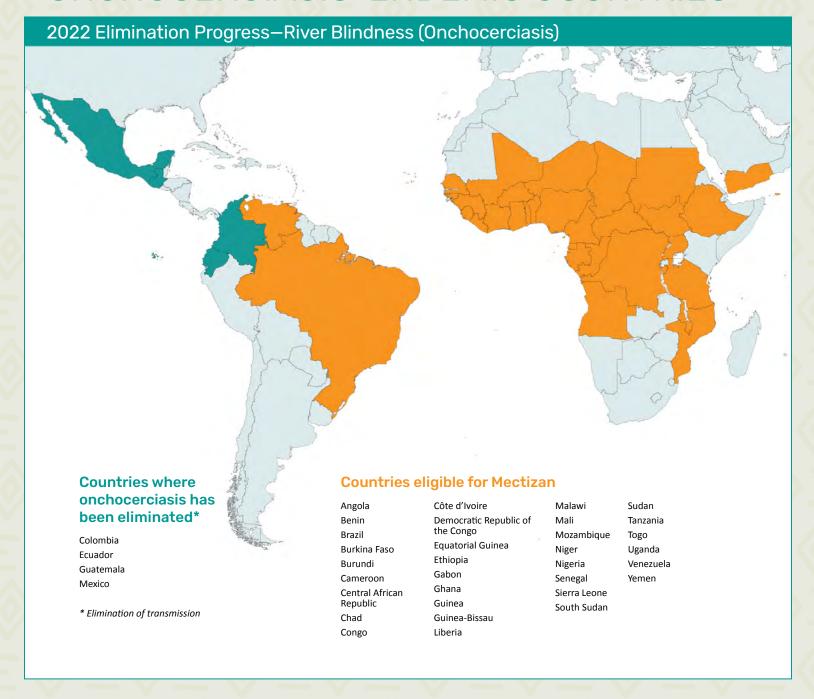
MDP at 35: A Look Back







ONCHOCERCIASIS-ENDEMIC COUNTRIES





LYMPHATIC FILARIASIS ELIMINATION IN 2022

CONTENTS

Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination Progress—River Blindness

2022 Elimination
Progress—
Lymphatic Filariasis

2022 News

MDP at 35: A Look Back





Mectizan® Donation

2022 Elimination Progress-Lymphatic Filariasis





Maxwell Masa (top) must carefully manage his LF-swollen leg to prevent pain and infection. In 2020 Malawi eliminated LF, sparing future generations. (Photos by Peter Ngwale and Virginia Murray)

In 2022, 164.6 million treatments were approved for LF elimination worldwide. Of these, 103 million were approved in African countries where Mectizan and albendazole are co-administered, and 61.6 million were approved in countries where river blindness is not endemic for triple therapy—also known as IDA—with Mectizan (ivermectin), DEC (diethylcarbamazine), and albendazole.



Application approvals for LF elimination in onchocerciasis-endemic countries under treatment with Mectizan and albendazole

In Africa where Mectizan (donated by Merck) and albendazole (donated by GSK) are co-administered for LF elimination, the 103 million treatments approved in 17 countries included 39.2 million Mectizan treatments for distribution in communities where LF and river blindness are co-endemic and 63.9 million treatments for distribution in communities endemic for LF only.

Benin, Cameroon, Mali, and Uganda continue 5-year post-treatment surveillance activities to ensure that LF has been eliminated as a public health problem based on WHO requirements for validation. They are well on their way to joining Malawi, Togo, and Yemen in successfully eliminating LF as a public health problem.



Application approvals for the implementation of IDA for LF elimination in countries where onchocerciasis is not co-endemic

In addition to the unlimited donation of Mectizan for the global elimination of river blindness, and the elimination of LF in African countries and Yemen co-endemic for river blindness, in 2017 Merck & Co., Inc. committed up to 100 million Mectizan treatments annually through 2025 for the implementation of triple therapy to accelerate LF elimination in countries where river blindness is not endemic.

A total of 61.6 million treatments were approved in 2022 for India, Indonesia, Malaysia, Nepal, the Philippines, and Samoa. The total number of countries that have adopted IDA as a strategy to eliminate LF is now 21.

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> **2022 Elimination Progress**— **Lymphatic Filariasis**

> > **2022 News**

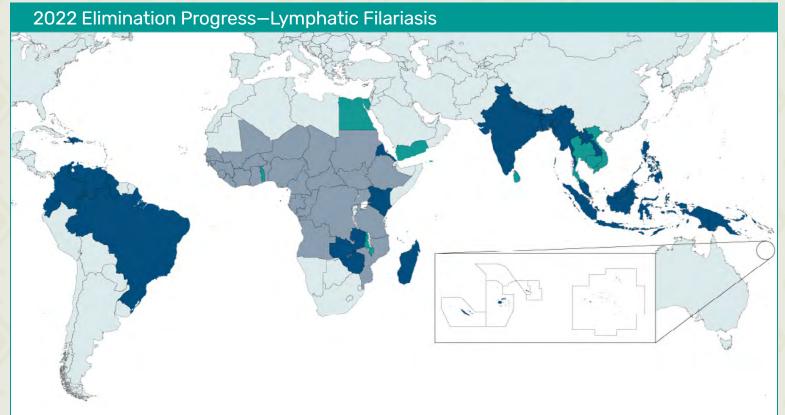
MDP at 35: A Look Back







LYMPHATIC FILARIASIS-ENDEMIC COUNTRIES



Countries where LF has been eliminated*

Cambodia Sri Lanka Thailand Cook Islands Egypt Togo Kiribati Tonga Malawi Vanuatu Maldives Vietnam Marshall Islands Wallis and Futuna Niue Yemen Palau

Countries eligible for Mectizan and albendazole

of the Congo

Angola Equatorial Nigeria Guinea Benin Senegal Ethiopia Burkina Faso Sierra Leone Gabon South Sudan Cameroon Ghana Central African Sudan Republic Guinea Tanzania Chad Guinea-Bissau Uganda Liberia Congo Côte d'Ivoire Mali Democratic Republic Mozambique

Niger

Countries & territories eligible for Mectizan, DEC, and albendazole (IDA)*

American Samoa French Polynesia Nepal Guyana Bangladesh New Caledonia Haiti Papua New Guinea Brazil India Brunei Darussalam **Philippines** Comoros Indonesia Samoa Dominican Republic Kenya Sao Tome and Principe Eritrea Lao PDR Timor-Leste **Federated States** Madagascar Tuvalu of Micronesia Malaysia Zambia Zimbabwe Myanmar

^{*} Elimination as a public health problem

^{*} Countries in italics have been approved for Mectizan



PROGRAM DOWNSCALING FOR LF ELIMINATION

CONTENTS

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> **2022 Elimination Progress**— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back







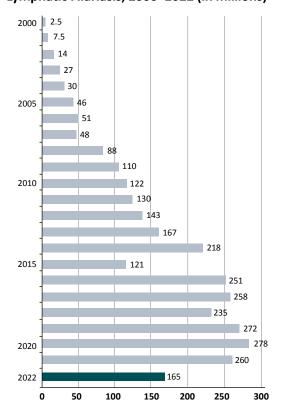
2022 Elimination Progress-Lymphatic Filariasis

The number of people who no longer need treatment with Mectizan and albendazole for LF elimination increased from 191.8 million in 2021 to a remarkable 265.4 million in 18 countries (Table 2). Among those, approximately 71.3 million will continue to receive Mectizan for river blindness.

Table 2: Mectizan + Albendazole Treatment Stopped for **Lymphatic Filariasis**

Country	LF districts no longer needing treatment	Total LF districts	Population in LF districts no longer needing treatment	Population still receiving treatment for onchocerciasis in districts where LF treatment is stopped
Benin**	48	48	5,726,113	3,257,412
Burkina Faso	62	70	20,011,433	231,088
Cameroon**	144	144	18,244,861	12,190,347
Cote d'Ivoire	68	99	17,987,288	14,510,087
DRC	27	244	5,582,706	1,381,929
Ethiopia	52	100	3,620,595	2,003,846
Ghana	109	117	14,765,211	4,061,845
Malawi*	28	28	18,880,575	3,236,897
Mali**	75	75	23,570,466	7,034,518
Mozambique	62	114	12,547,131	0
Niger	55	56	20,379,529	0
Nigeria	142	583	36,566,874	6,923,873
Senegal	41	51	9,120,027	0
Sierra Leone	12	16	8,086,188	5,864,298
Tanzania	112	119	30,240,027	7,272,927
Togo*	9	9	1,685,579	1,276,212
Uganda**	69	69	18,295,457	1,945,963
Yemen*	11	11	130,968	78,067
Total	1,126	1,953	265,441,030	71,269,309

Figure 4: Treatments Approved for Lymphatic Filariasis, 2000-2022 (in millions)



^{*} Validated by WHO as having achieved elimination as a public health problem.

^{**} All endemic districts are under post-treatment surveillance (PTS).

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back







MALAWI'S ELIMINATION OF LF PROTECTS FUTURE GENERATIONS

This year we celebrated a marvelous achievement: after decades of hard work, Malawi eliminated lymphatic filariasis (LF) as a public health problem. This is a huge victory, but it came too late for people who were already affected by LF. People like Blandina Banda.

Blandina is a fashionable young mother whose long skirt swishes as she walks through the crowded Thyolo marketplace. But it's a hot day, and she's wearing the long skirt for a reason: Blandina contracted LF as a child, and now her right leg and foot are severely and permanently swollen.

LF is a neglected tropical disease caused by a mosquito-borne parasite. Among other symptoms, LF can lead to painful swelling in limbs along with thickened and hardened skin that is prone to infection and frequent acute attacks. The disfigurement can lead to stigma, shame, and ostracism.

In school, Blandina was bullied to the point that she finally guit, and later in life her son's father abandoned the family due to embarrassment. Now a single mother, she lives with her little boy, Elvis, and a foster daughter, making a meager living as a mobile money agent in town.

She often feels angry about her difficult childhood, about the stigma she faces as an adult, and about doctors' inability to address her problem before it progressed. When the MDP team visited her, she welcomed the opportunity to tell her story as a way to advocate for change.

Blandina's strong will and determination to succeed allowed her to carve out a life for her small family despite her disability. The future is uncertain, but she takes comfort in one fact: her son will grow up without the threat of suffering the effects of LF infection.







Watch our video to learn more about how Malawi gathered the political will to end LF and continue the fight against river blindness. bit.ly/MalawiWill

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination **Progress**— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back







THE MECTIZAN EXPERT COMMITTEE/ ALBENDAZOLE COORDINATION



Members of the MEC (front row) and guests at MEC68 in Lilongwe, Malawi. (Photo by Timothy Chikupetah)



Learn more about the MEC and their affiliations at www.mectizan.org/MEC. The Mectizan Expert Committee/Albendazole Coordination (MEC/AC) is the independent technical body of experts providing oversight for the donation of Mectizan and, for lymphatic filariasis elimination, coordination of the codistribution of Mectizan and albendazole (donated by GSK). The MEC/AC meets in the spring and fall of each year.

In 2022, the MEC/AC included: MEC Chair, Prof. Gilbert Burnham (USA); LF expert Prof. Yaya Coulibaly (Mali); parasitologist and LF expert Prof. Monique Dorkenoo-Agbeko (Togo); LF expert Dr. Ramaiah Kapa (India); behavioral health scientist Dr. Alison Krentel (Canada); parasitologist Dr. Tom Nutman (USA); entomologist, parasitologist, and onchocerciasis expert Prof. B.E.B. Nwoke (Nigeria); and parasitologist and LF and onchocerciasis expert Dr. Sébastien Pion (France).

LOOKING TO THE FUTURE



ONCHO GOALS: The 2021-2030 WHO NTD Road Map targets for verification of elimination of river blindness transmission:











LF GOALS: The 2021-2030 WHO NTD Road Map targets for validation of elimination of LF as a public health problem:









MDP is 100% committed to providing Mectizan for river blindness and lymphatic filariasis elimination in African countries where both diseases are co-endemic—as much as needed, for as long as needed. We also remain committed to fulfilling the limited donation of Mectizan for the ongoing "triple therapy" strategy to accelerate elimination of lymphatic filariasis in eligible countries where river blindness is not endemic.

In 2023, we look forward to celebrating more countries as they make progress toward eliminating these debilitating diseases.

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination **Progress**— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back











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mectizan.org

The Mectizan Donation Program is an international program to eliminate river blindness and lymphatic filariasis, primarily funded by Merck & Co., Inc.,* with support from GlaxoSmithKline.

Through the Mectizan Donation Program, Merck & Co., Inc. donates Mectizan® for the elimination of the transmission of onchocerciasis and for the elimination of lymphatic filariasis (LF) as a public health problem. For the elimination of LF where onchocerciasis is co-endemic in Africa and Yemen, Mectizan is co-administered with albendazole, donated by GSK. In countries eligible for "triple therapy," Mectizan and albendazole are co-administered with diethylcarbamazine (DEC) to accelerate LF elimination in some communities.

All photos @Mectizan Donation Program unless otherwise noted.

* Merck & Co., Inc. is known as MSD outside the USA and Canada.

On the front cover, some highlights from 35 years of Mectizan. Clockwise from top left: Worker fulfills a Mectizan order in 2018 at the National Procurement Centre for Essential Drugs and Medical Devices in Yaoundé, Cameroon. (Photo by William Nsai) Schoolboy holds a sign in 2011 during a celebratory parade in Chiapas, Mexico. (Photo by Joni Lawrence) Child displays a Mectizan tablet during mass drug administration in the Democratic Republic of the Congo, 2016. (Photo by Tobias Pflanz for CBM) Community drug distributor Maureen Mbewe poses in 2022 in front of her home in the Thyolo region of Malawi. (Photo by Peter Ngwale)

Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination Progress—River Blindness

2022 Elimination Progress— Lymphatic Filariasis

2022 News

MDP at 35: A Look Back







MDP CELEBRATES 35 YEARS

Since the Mectizan Donation Program was established in 1987, more than 5 billion treatments for river blindness and lymphatic filariasis have been approved.

CONTENTS

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back





Community drug

distributors head out

to work carrying dose

ooles in Nasarawa

Previous page: Safe

from transmission of

river blindness in Kebb State, Nigeria. (Photos

State, Nigeria.

by William Nsai)





Before Mectizan® (ivermectin), vector control through aerial larviciding was the primary strategy to control the disease. The only medications available had the potential for dangerous side effects.

In the early 1980s, scientists at Merck Research Laboratories recognized that their anti-parasitic drug ivermectin could be effective against river blindness in humans. Clinical trials began.

In 1987, following approval for the treatment of river blindness by the French regulatory authorities, Merck & Co. Inc.* announced the donation of Mectizan for the control of river blindness "as much as needed, for as long as needed." The Mectizan Donation Program and the Mectizan Expert Committee were established to provide medical and technical oversight to promote independent allocation and good use of the donation.

Merck thus became the first company to donate a medicine to treat millions of people and control a neglected tropical disease (NTD). Merck's example launched a wave of "pharmaco-philanthropy" that led to donations for other NTDs, and established NTDs as a new sector of global health.

Mectizan is safe and easy to administer in a single dose once a year, making it ideal for mass distribution. With this breakthrough medication, health professionals began to hope for a brighter future for those suffering from the severe itching, visual impairment, and blindness caused by infection.

By 2016, 4 of the 6 endemic countries in the Americas had eliminated transmission of river blindness through consistently high-treatment coverage with Mectizan.

When Mectizan was first donated, elimination of transmission in Africa was not considered possible. Mectizan was distributed to relieve suffering by controlling the disease. Thirty-five years later, however, transmission of the disease is being eliminated in many parts of the continent through mass treatment with Mectizan. In 2021, this development led to WHO setting a new target in the 2030 NTD Road Map: elimination of transmission of river blindness in endemic countries.

In 1998, the mandate of the Mectizan Donation Program was expanded to combat lymphatic filariasis (LF) following WHO's recommended strategy to co-administer Mectizan and albendazole in countries where LF is co-endemic with river blindness. GSK joined the partnership by donating albendazole for LF elimination.

In 2017, Merck committed to facilitate access to ivermectin by providing up to an additional 100 million Mectizan treatments annually through 2025 for countries implementing "triple therapy" with ivermectin, diethylcarbamazine (DEC), and albendazole to accelerate LF elimination in eligible countries non-endemic for river blindness.

Learn more about Mectizan's history at www.mectizan.org.

*Merck & Co., Inc. is known as MSD outside the USA and Canada.

Message from Dr. Yao Sodahlon, Director

The Global Reach of the Mectizan Donation Program

2022 Elimination Progress—Overview

2022 Elimination Progress—River Blindness

2022 Elimination
Progress—
Lymphatic Filariasis

2022 News

MDP at 35: A Look Back











HOW WE GET IT THERE

Mectizan is donated and shipped free of charge to eligible countries. Ministries of Health submit an application to WHO and MDP. Upon review and approval by the Mectizan Expert Committee (MEC), the shipment is initiated by Merck. Mectizan tablets are manufactured by MSD* in the Netherlands, then sent to the beneficiary country for distribution. Learn more about the Mectizan supply chain at www.mectizan.org.

BEYOND MEDICINE DONATION

Merck and MDP provide gap funding for mass drug administration and monitoring & evaluation in countries where there is a lack of domestic and external financial support.



MDP provides external support to select partners to facilitate collaboration on river blindness and LF elimination on topics such as cross-border collaboration.

MDP also works to foster strong partnerships with key stakeholders, including Merck, GSK, Eisai, endemic countries, WHO and its regional offices, NGOs, and the donor community. Partnership is the driving force behind the success achieved toward river blindness and lymphatic filariasis elimination.







Researchers in Kebbi State, Nigeria, collect blackflies for testing. (Photo by William Nsai)

MDP at 35: A Look Back | iii

Message from Dr. Yao Sodahlon, Director

The Global Reach of the **Mectizan Donation Program**

> 2022 Elimination **Progress—Overview**

2022 Elimination **Progress—River Blindness**

> 2022 Elimination Progress— **Lymphatic Filariasis**

> > **2022 News**

MDP at 35: A Look Back







OUR SUCCESSES



Millions of people around the world no longer need treatment for these terrible diseases: approximately 46 million people are safe from river blindness and 265 million from LF.



Malawi, Togo, and Yemen have been validated by WHO for eliminating lymphatic filariasis as a public health problem.









Colombia, Ecuador, Guatemala, and Mexico have been verified by WHO for eliminating transmission of river blindness.



The successful control of river blindness led to a paradigm shift. The disease is now targeted by WHO for elimination of transmission worldwide, which will end the disease forever.