Ending neglected tropical diseases

IFPMA member companies support eliminating and controlling neglected tropical diseases over the next decade through landmark donations.
A life-changing pledge:

IFPMA members to
donate over 1.4 billion
treatments1 annually
for ten years to control
or eliminate nine major
NTDs

© Mark Tuschman, Pfizer
One billion people worldwide – or one person in seven – suffer from neglected tropical diseases (NTDs). These illnesses primarily affect poor people in tropical and subtropical areas of the world. Nine NTDs (human African trypanosomiasis, Chagas disease, lymphatic filariasis, soil-transmitted helminthiases, onchocerciasis, schistosomiasis, leprosy, fascioliasis, and blinding trachoma) represent more than 90% of the global NTD burden.

NTDs kill or disable millions of people every year. At such level of impact, NTDs can no longer be ignored. These illnesses affect both children and adults for life, often lead to stigmatization, and can prevent children from developing to their fullest potential. As long as NTDs continue to be endemic in poor countries, they will remain a contributor to a vicious cycle of poverty in these regions.

Eliminating or controlling NTDs is achievable. The World Health Organization (WHO) has set 2020 targets to end these nine NTDs. Success relies on a multi-stakeholder approach which integrates elements such as environmental improvements, boosting capacity-building efforts, effective health policies, better screening, availability of quality, safe and effective medicines, and, in some cases, further research and development (R&D).

Doing our part: research-based pharmaceutical industry to donate an average of over 1.4 billion treatments a year to meet these goals.

As part of our commitment to improve global health, IFPMA members have pledged to donate an average of more than 1.4 billion treatments for each of the ten years from 2011 to 2020. The total of over 14 billion treatments over this period will help eliminate or control the nine NTDs that represent more than 90% of the global NTD burden. This pledge can only reach patients through strong commitment from both concerned countries and implementation partners.

IFPMA members holistic fight against NTDs. The research-based pharmaceutical industry fights NTDs in several ways. Firstly, through cutting-edge research and development (R&D) IFPMA members are currently working on 82 projects either independently or in product development partnerships (PDPs). A recent report shows the industry was the second largest funder of R&D for neglected diseases in 2010. Furthermore, as a partner in global health, IFPMA members’ work with the WHO and other partners to implement capacity-building efforts in developing countries. These efforts are complemented by medicine donation programmes, several of which date back decades.

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1 A treatment is defined in the average number of medicines required to cure or prevent one of the nine NTDs.

**Commitment of pharmaceutical companies:**

Estimated number of treatments to be donated

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of treatments in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>988,119,804</td>
</tr>
<tr>
<td>2012</td>
<td>1,138,161,660</td>
</tr>
<tr>
<td>2013</td>
<td>1,466,004,495</td>
</tr>
<tr>
<td>2014</td>
<td>1,673,246,832</td>
</tr>
<tr>
<td>2015</td>
<td>1,614,129,890</td>
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<tr>
<td>2016</td>
<td>1,639,148,067</td>
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<tr>
<td>2018</td>
<td>1,571,679,388</td>
</tr>
<tr>
<td>2019</td>
<td>1,450,229,614</td>
</tr>
<tr>
<td>2020</td>
<td>1,379,734,967</td>
</tr>
</tbody>
</table>

Total 2011-2020: 14,536,053,379

Average per Year: 1,453,605,338

* Nifurtimox, generally used as 2nd-line drug.

* The Bill and Melinda Gates foundation is also contributing.
Ending neglected tropical diseases

The WHO 2020 NTD goals and the role of the research-based pharmaceutical industry

In 2010, WHO confirmed the adverse socioeconomic impact of NTDs on development and quality of life at all levels. WHO recommends five public health strategies for the prevention, control, or elimination of NTDs: (i) preventative chemotherapy; (ii) intensified case management; (iii) vector control; (iv) provision of safe water, sanitation and hygiene; and (v) veterinary public health. Of these, preventative chemotherapy and intensified case management are directly relevant to the research-based pharmaceutical industry’s medicine donation programmes.

There are six NTDs for which preventative chemotherapy (i.e. treatment is applied to the whole population at risk, not just those infected) is an important approach. For diseases such as lymphatic filariasis, onchocerciasis (river blindness), soil-transmitted helminthiasis, schistosomiasis, fascioliasis, and blinding trachoma, the adequate supply of medicines can lead to elimination.

For those diseases where no preventative medicines exist, intensive case management (ICM) can be used. ICM involves caring for infected individuals and those at risk of infection. This strategy depends on early diagnosis, treatment to fight infection and reduced morbidity, and management of complications. ICM diseases are Chagas disease, human African trypanosomiasis (HAT, also known as sleeping sickness), and leprosy.

While the research-based pharmaceutical industry has an important role to play, it is only one of the global “community of partners” fighting NTDs. Governments and other healthcare stakeholders will also need to increase funding for country NTD programmes, improve water quality and sanitation, and strengthen their capacity-building and education efforts to reduce disease burden.

Disease profiles: why these NTDs matter

This publication showcases nine NTDs where the industry is playing a vital role in achieving control or elimination. The following disease profiles demonstrate why these illnesses matter, and how the research-based pharmaceutical industry’s donations are making a difference to the lives of hundreds of millions of people in the developing world.

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5 WHO, Accelerating work to overcome the global impact of neglected tropical diseases. A roadmap for implementation”, 2012.
**Lymphatic filariasis (LF)**

**Target 2020: Global elimination**

**Disease:** LF is a severely debilitating and disfiguring disease, which can lead to permanent disability. Caused by parasitic worms, it is usually acquired in childhood. However, visible symptoms only occur later in life.

**Impact:** An estimated 120 million people in 72 countries suffer from the disease; 1.39 billion (15% of the world’s population) are at risk of infection.

**Treatment:** Recommended treatment is a single dose of two medicines given together. Albendazole and ivermectin are used in areas where onchocerciasis (river blindness) is also endemic. Diethylcarbamazine citrate (DEC) is used with albendazole where onchocerciasis is not co-endemic. For over ten years, the research-based pharmaceutical industry has spearheaded a global effort to eliminate LF through public-private partnerships and the provision of free medicines.

**Elimination strategy:** The WHO set the target to eliminate LF by 2020. To interrupt transmission, mass treatment programmes are needed in endemic areas treating the entire at risk population. Typically, an annual dose of two drugs given together is needed for at least five years.

**Donations:**

- In 1998, GlaxoSmithKline pledged unlimited amounts of albendazole until the disease is eliminated.

- Also in 1998, Merck & Co. pledged unlimited amounts of ivermectin for the elimination of LF.

- In 2010, Eisai announced it would produce and supply for free to the WHO up to 2.2 billion 100 mg tablets of DEC between 2013 and 2020. Eisai has stepped up to manufacture this medicine despite having no history of making the medicine. Never before has a company agreed to produce a medicine solely for the purposes of an NTD elimination program. Eisai’s DEC will be produced at its state-of-the-art facility in Vizag, India, and supply will begin in 2013. The product will reach over 800 million patients in the developing world over the course of the programme.

- The Bill & Melinda Gates Foundation, Sanofi and Eisai have announced a donation of 120 million DEC tablets to the WHO for their Global Lymphatic Filariasis Elimination programme. The consortium, the first of its kind, sees the partners jointly financing the donation which will allow the WHO to provide treatment of 30 million people (2 tablets per person, once a year for 2 years). The donation will ensure a stable supply of DEC to the WHO Global Lymphatic Filariasis Elimination programme for 2012 and 2013, after which Eisai will begin its Lymphatic Filariasis Elimination Partnership with WHO and continue to provide DEC at “price-zero” until 2020 (see above).

As a result these ongoing pledges, there will soon be no shortage of medicines for the preventative treatment of LF.
**Partnerships in Action: the Global Alliance to Eliminate Lymphatic Filariasis (GAELF)**

The GAELF is a partnership initiated by the WHO and GlaxoSmithKline in 1998 and with Merck & Co., joining later. The GAELF evolved into a global partnership between international organizations in the public and private sectors, academia and non-governmental organizations working in partnership with ministries of health in all countries where lymphatic filariasis (LF) is endemic.

In addition to the donation programme of over a billion treatments, Merck & Co., Inc. and GlaxoSmithKline provide financial grants to support partners in programme research, coalition-building, workshops and communications.

Since its initiation, the GAELF has become the most rapidly scaled-up Mass Drug Administration programme in public health history. During 2010, the WHO reported over 466 million people were treated worldwide through this programme. In a 2008 study published in PLoS Neglected Tropical Diseases, researchers found that the LF elimination effort prevented 6.6 million children from acquiring the disease.

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7 WHO, WER, 26 August 2011

Onchocerciasis (river blindness)
Target 2020: Regional elimination

Disease: Commonly known as river blindness, onchocerciasis is an infectious disease caused by infection of a parasite transmitted through the bite of infected blackflies. The larval worms move through the body, and when they die cause a variety of conditions, including skin rashes, lesions, intense itching, skin depigmentation and blindness. It is the world’s second-leading infectious cause of blindness.

Impact: The WHO estimates that about half a million people have lost their eyesight due to river blindness.

Treatment: In some countries, onchocerciasis has been controlled through spraying of blackfly breeding sites with insecticide. More broadly, the disease is treated with an annual dose of ivermectin, which also relieves the severe skin itching caused by the disease. Ivermectin kills the young worms and with sufficient coverage on the community level, can prevent transmission. Treatment of LF and onchocerciasis can be combined through the administration of ivermectin + albendazole in areas where both are endemic.

Elimination strategy: WHO estimates that elimination by 2015 is feasible in Latin America. Furthermore, by 2020, 31 countries affected by onchocerciasis in Africa may have achieved elimination. Already some countries and sub-national areas have been able to stop treatment based on evidence that onchocerciasis has been eliminated. Further success will depend on a number of factors, including maintaining high treatment coverage with ivermectin during the lifespan of the adult worm, supporting government ownership to sustain high treatment coverage and establishing community directed treatment to help strengthen weakened health infrastructure and depleted human resources in post-conflict areas.

Donations: Merck donates as much ivermectin as is needed for as long as necessary.

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Partnerships in Action:
Merck Mectizan® Donation Programme
The Merck Mectizan® Donation Programme (MDP) was launched in 1987, when Merck & Co., announced that it would donate Mectizan® (ivermectin) for the treatment of onchocerciasis to all who need it for as long as necessary. A multi-sectoral partnership was established with governments in countries where onchocerciasis is endemic, their ministries of health and other national and international stakeholders, including the WHO, to ensure appropriate infrastructure, distribution and support. The Mectizan® Donation Programme is the longest-running, disease-specific drug donation programme and public-private partnership of its kind in history, and is widely regarded as one of the most successful public-private health collaborations in the world.

Since the inception of the programme in 1987, Merck has donated nearly 1 billion treatments with Mectizan® for river blindness. The programme currently provides 100 million treatments annually through river blindness programs in Africa, Latin America and Yemen.

Soil transmitted helminthiases (STH)  
Target 2020: Control

**Disease:** STH is more commonly known as an intestinal worm infection and largely affects children. It is due to one or more intestinal parasitic worms. The persistence of STH is closely linked to the contamination of the environment, due to inadequate sanitation with faeces containing the eggs of parasitic worms. The symptoms of STH infections are non-specific and only become evident when the infection is particularly severe. Symptoms include nausea, fatigue, abdominal pain and loss of appetite, which aggravate malnutrition and increase anaemia rates. They impede children’s physical growth and cognitive development. It is one of the most common infections worldwide affecting the most deprived communities.

**Impact:** More than one billion people are infected, of whom at least 300 million suffer from severe morbidity.

**Treatment:** Access to safe water and proper sanitation can reduce the prevalence of the disease. The most effective medical treatments are mebendazole or albendazole.

**Control strategy:** The WHO aims to control this disease by 2020 and forecasts that 7.3 billion tablets10 (for STH and lymphatic filariasis) are needed to reach this goal.

**Donations:**
- Johnson & Johnson announced that it would quadruple mebendazole donations over the next ten years, progressively reaching 200 million doses annually from 2014.
- GlaxoSmithKline extended its albendazole donation programme, previously restricted to LF, to soil transmitted helminthiases. This additional commitment represented 400 million tablets a year, on top of the 600 million tablets already pledged for LF.

**Partnerships in Action:**

**Johnson & Johnson’s Children Without Worms**

Johnson & Johnson’s global programme, Children Without Worms, created in partnership with the Task Force for global health, worked with national and international partners to treat up to 25 million children a year with mebendazole in 2011. The programme also advocates hygiene, education and increased access to water and sanitation facilities as part of a comprehensive strategy to reduce the global burden of soil-transmitted helminthiases (STH). The programme is active in countries with high soil-transmitted helminthiases (STH) prevalence. The original eight countries are: Bangladesh, Cambodia, Cameroon, Cape Verde, Lao People’s Democratic Republic, Nicaragua, Uganda and Zambia. Other countries will be added to this list as the program expands with the additional commitment of medicines.

GlaxoSmithKline has pledged to donate 400 million tablets each year of albendazole to the WHO to treat children at risk of soil-transmitted helminthiases (STH). Togo and Rwanda have received early shipments of albendazole treatments to begin scale up their school-based de-worming efforts. Mozambique, Namibia, Uganda, Burkina Faso and others are expected to begin programmes in 2012. To meet its commitment, GlaxoSmithKline has increased its production capacity of albendazole in South Africa.

GlaxoSmithKline and Johnson & Johnson will be collaborating closely with Children Without Worms to maximize the impact of the combined 600 million doses of treatments now available for the control of STH that is affecting the hundreds of millions of underserved children around the world.

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10 Figure include STH and LF diseases given that albendazole also treats LF
**Schistosomiasis**

**Target 2020: Regional elimination (contribute to elimination by at least 75% coverage of school-age children requiring preventive chemotherapy for schistosomiasis)**

**Disease:** Schistosomiasis is a parasitic disease. Humans become infected through contact with skin-penetrating parasitic worms in water. The disease can lead to chronic illness that damages internal organs. In children, it can impair growth and cognitive development. Children are the most heavily infected population. Schistosomiasis is the second most socioeconomically devastating parasitic disease after malaria. Individuals in developing countries who cannot access proper sanitation facilities are often exposed to contaminated water containing the schistosomiasis parasite.

**Impact:** More than 220 million people are infected worldwide, of which 100 million are children.

**Treatment:** The major medical intervention used to control schistosomiasis is praziquantel, accompanied by the provision of safe water and adequate sanitation.

Closing the Schistosomiasis medicines gap: According to WHO, a major milestone for 2020 will be “at least 75% national coverage in all countries requiring preventive chemotherapy”.

**Donations:**
- 20 million praziquantel tablets are donated annually by Merck KGaA under its current ten-year programme.
- Merck KGaA recently announced a considerable increase of its donation of praziquantel tablets, reaching 250 million tablets annually in the medium term depending on the availability of high quality active pharmaceutical ingredient (API) of praziquantel. Merck KGaA now intends to continue its efforts to fight schistosomiasis indefinitely.
- Donations of praziquantel have enabled treatment to be significantly scaled up in recipient countries.

**Partnerships in Action:**

**Merck KGaA’s collaboration programme**

Under the current Merck Praziquantel Donation Programme (MPDP), about 19 million children have been treated in 15 African countries since 2008. Merck KGaA plans to increase its annual donation of tablets from 20 million to 250 million tablets per year until elimination which will allow to treat about 100 million children per year and which contributes to the elimination of the disease by 2020. Praziquantel is known to be the most effective therapy currently available for schistosomiasis infections. The medicine has a very good safety profile, is easily administered as a single dose and is well tolerated. The WHO coordinates local distribution.

In addition, Merck KGaA will financially support a WHO-led school awareness programme in Africa. The objective of which is to educate children about the consequences of schistosomiasis and ways to prevent the disease.
**Blinding trachoma**

**Target 2020: Global elimination**

**Disease:** Blinding trachoma is a bacterial infection of the eye that is spread through contact with eye discharge from an infected person. Untreated, this condition can significantly affect eyesight and even cause blindness. Environmental risk factors influencing transmission of the disease include poor hygiene, crowded households, water shortage and inadequate toilet facilities.

**Impact:** An estimated 84 million people suffer from blinding trachoma, of which 8 million are visually impaired.

**Treatment:** Blinding trachoma is controlled by the use of the SAFE strategy: eyelid surgery (S); treatment with antibiotics (A); facial cleanliness (F); and environmental improvement (E).

**Elimination strategy:** The WHO aims to eliminate the disease by 2020 through the implementation of the SAFE strategy.

**Donations:**
- Pfizer is committed to supplying azithromycin needed for implementation of the SAFE strategy to help meet the 2020 goal to eliminate blinding trachoma. Actual donations through 2020 are dependent on national programme ownership, the use of antibiotics as part of the WHO-recommended SAFE strategy, continued partner commitment, and prevalence mapping.
- Since 1998 Pfizer has provided 145 million treatments of azithromycin for treatment and prevention of the disease in 18 countries.

**Partnerships in Action:**

**The International Trachoma Initiative (ITI)**

Pfizer, the WHO, the Bill and Melinda Gates Foundation and the Edna McConnell Clark Foundation are among the ITI partners who share the goal of eliminating trachoma by 2020.

In March 2009, ITI and the Task Force for Child Survival and Development announced that they would join forces to scale up efforts to eliminate trachoma. ITI supports the implementation of the WHO’s recommended SAFE strategy. A comprehensive public health approach that combines treatment and prevention, including sight-saving surgery, mass treatment with the Pfizer-donated antibiotic azithromycin, facial cleanliness education, and environmental improvements to increase access to clean water and improved sanitation.

ITI has trained thousands of healthcare workers who have performed more than 416,000 surgeries to treat advanced cases of trachoma. Morocco became the first country to complete the campaign for trachoma control in 2006, and is now working toward WHO certification to signify that blinding trachoma has been eliminated as a public health problem. To date Pfizer along with the WHO and the Bill and Melinda Gates Foundation have led the initiative to ensure the provision of antibiotics needed for the treatment of trachoma.

Pfizer is committed to providing azithromycin to help achieve the WHO 2020 elimination goal. However, to achieve the shared goal of elimination multiple partnerships in various sectors such as water management, sanitation and education are particularly necessary.
Human African Trypanosomiasis (HAT or sleeping sickness)
Target 2020: Global Elimination

Disease: HAT is one of the most complex endemic tropical diseases. It is a parasitic disease spread by the bite of the 'Glossina' insect, or tsetse fly. Initial symptoms, when the treatment has the greatest chance of success, are often mild or nonspecific and may include headaches, fever, weakness, sweating, pain in the joints, and stiffness. However, patients often seek help only when the disease is already advanced, and has penetrated the brain, eventually causing the daytime drowsiness, which gives the disease its name. Untreated HAT can be fatal with death following prolonged agony.

Impact: 60 million people in Africa are at risk of infection.

Treatment: A number of different drugs are required to treat HAT: eflornithine, melarsoprol, pentamidine, nifurtimox and suramin. This is partly due to different variants of the disease and the need for different drugs at different stages of the disease. This is one of the NTDs where active screening of individual patients is required for the early detection of cases and for the most effective treatment. Therefore, much of the burden to effectively tackle this disease rests with local healthcare systems. Intervention requires mobile teams of specially trained health workers.

Elimination strategy: The WHO seeks to eliminate HAT by 2020 thanks to effective active and passive screening programmes, combined with free drug treatment (see below) for positively identified patients, and capacity-building of front line health workers.

Donations:
- Sanofi pledged unlimited amounts of eflornithine, melarsoprol and pentamidine to the WHO until 2020.
- Bayer is committed to supply suramin and nifurtimox to the WHO for the treatment of HAT.

Partnerships in Action:
Sanofi and Bayer with the WHO
Since 2001, Sanofi has provided over 1.5 million vials of melarsoprol (Arsobal), pentamidine (Pentacarinat) and eflornithine (Ornidyl) and over 170,000 patients have been treated for human African trypanosomiasis (sleeping sickness) which, unless treated, is generally fatal.

During this same period, Bayer has provided free of charge suramin (Germanin™) and nifurtimox (Lampit™) to the WHO to treat African sleeping sickness in the early stages of the disease.

The WHO coordinates and finances (thanks to the partnership with Sanofi) the distribution of medicines to affected countries, and provides kits, prepared by Médecins Sans Frontières logistics, containing complete treatment packs of eflornithine and nifurtimox, together with the necessary materials (perfusion fluids IV giving sets, needles, gauze, adhesive tape) for treatments to be administered safely.

Because sleeping sickness affects patients living in remote areas, mobile medical teams have been organized and are specially trained and equipped to detect the disease, and arrange for treatment. These actions aim to ensure screening and diagnosis of the disease at the earliest stage possible. As a result of these initiatives and others, since 2001 the annual incidence of sleeping sickness has decreased by over 60%, patient numbers decreased to 7,139 in 2010. Since 2001 the annual incidence of sleeping sickness has decreased by over 60%.
Leprosy

2020 Target: Global elimination

Disease: Leprosy, a chronic bacterial infection transmitted via droplets, from the nose and mouth, during close and frequent contact with untreated sufferers. Untreated, leprosy can cause progressive and permanent damage to the skin, nerves, limbs and eyes. For centuries, people suffering from leprosy were subject to discrimination, stigmatization and social exclusion.

Impact: 2011 estimates neared 200,000 documented cases.

Treatment: Early diagnosis and treatment with multidrug therapy (MDT) remain key elements in eliminating the disease as a public health concern. MDT has been made available free of charge to all patients worldwide through donations from Novartis and the Novartis Foundation for Sustainable Development since 1995 and since 2000 respectively. To reach all patients, treatment of leprosy needs to be fully integrated into general health services and political commitment is critical.

Elimination strategy: The WHO seeks to eliminate this disease by 2020. Maintaining the free supply of medicines used for multidrug therapy is a key to fulfilling this goal.

Donations:
- The Novartis Group (Novartis Pharma, Novartis Foundation for Sustainable Development and Sandoz) provides high-quality multi-drug therapy (MDT) free of charge to all leprosy patients globally through the WHO.

Partnerships in Action: Novartis Foundation for Sustainable Development

The Novartis Foundation has supported national health ministries, the WHO and NGOs in field programmes since the mid-1980s. More than 14 million people have been cured of leprosy since 1985, over 4.5 million of them with drugs provided free of charge by Novartis. As recently as two decades ago, leprosy was a public health problem in 122 countries. Today the disease has been eliminated as a public health problem (i.e. reaching a prevalence rate of less than one case per 10,000 inhabitants) from all but three countries (Brazil, Nepal and Timor Leste).

Novartis also provides the funds for managing the donation, transport, insurance and independent quality control of MDT. The value of the Novartis MDT donation from 2000 to 2009 was USD 60 million. The Novartis Foundation has also helped simplify the provision of disability prevention services in communities. Many of the approaches devised by the Novartis Comprehensive Leprosy Care Association in India have now been incorporated in the government and NGO disability care packages.

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**Fascioliasis**

**2020 Target: Global elimination**

**Disease:** Fascioliasis is a food-borne trematode, also known as 'common liver-fluke'. People living in rural, agricultural villages in the Andean highlands of Bolivia and Peru have the highest rates of infection. In endemic countries, school children are at the highest risk of infection. Growing prevalence in human populations has prompted health authorities to address the problem with increased urgency. Fascioliasis is currently a health concern in more than 70 countries. Human infection occurs primarily through the ingestion of Fasciola larvae attached to raw or uncooked vegetables, such as watercress or water mint, or floating in drinking water.

**Impact:** Millions of people are infected with fascioliasis and an estimated 180 million are at risk.

**Treatment:** Fascioliasis infection is treated using a single dose of the medicine triclabendazole.

**Elimination strategy, donations, and partnerships in Action:** **Novartis and WHO**

As per WHO requests, Novartis donates triclabendazole for the treatment of infected individuals in endemic countries. The medicine is available free of charge upon application from ministries of health. Countries such as Bolivia, Egypt, Georgia, the Islamic Republic of Iran, Peru, Tajikistan, Vietnam and Yemen applied for donated triclabendazole and started treatment programmes.
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