Azithromycin 2025 Management Guide for Trachoma

How to successfully apply for, administer, and manage the azithromycin donation for trachoma elimination

International Trachoma Initiative

Above Photo: Esmael Habtamu from The Carter Center Trachoma Control Program is checking for signs of trachoma in North Mecha Woreda, Amhara region of Ethiopia. The Amhara region is the most endemic area in the most endemic country. *Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

Cover Photo: In Wolaita Sodo, South Ethiopia, a volunteer carefully measures a child against a height-based dosing pole to determine the correct azithromycin dosing during a mass drug administration (MDA) at a local school. *Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

Acknowledgments

This manual is a revised version of the *Zithromax® in the Elimination of Blinding Trachoma: A Program Manager's Guide* © 2010 ITI and the *Zithromax® Management Guide* © 2019 ITI. Thank you to the following individuals who have contributed their practical experience, technical expertise, and thoughtful input in the creation of this manual:

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ITI works in partnership with governments and international and local organizations to support the implementation of the SAFE strategy. Sincere thanks go to our co-workers in the districts and communities who demonstrate trachoma elimination in practice and whose leadership, dedication, and hard work are a source of inspiration for us all.

A publication of the International Trachoma Initiative

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A community drug distributor (CDD) holds a bottle of azithromycin during mass drug administration in Wandara Gale, South Ethiopia. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

List of Acronyms

AE — Adverse Event

AMG — Azithromycin Management Guide

CDDs — Community drug distributors

CMS — Central Medical Store

CO — Corneal opacity

C. trachomatis — Chlamydia trachomatis

ELC — Pfizer European Logistics Center

F&E— Facial cleanliness & Environmental improvement

FEFO — First Expiry, First Out

FIFO — First In, First Out

GET2020 — WHO Alliance for the Global Elimination of Trachoma by 2020

ICTC — International Coalition for Trachoma Control

ITI — International Trachoma Initiative

LMIS — Logistics management information system

MDA — Mass drug administration

MFTA — More-frequent-than-annual

MOH — Ministry of Health

MOU — Memorandum of understanding

NAAT — Nucleic acid amplification tests

NPC — National Program Coordinator

NTD — Neglected tropical disease

PCR — Polymerase chain reaction

POS — Powder for oral suspension

PQC — Product quality complaint

SAE — Serious adverse event

SAFE — Surgery, Antibiotics, Facial cleanliness, and Environmental improvement

SKU — Stock keeping unit

SOPs — Standard operating procedures

TEC — Trachoma Expert Committee

TEMF — Trachoma Elimination Monitoring Form

TEO — Tetracycline eye ointment

TF — Trachomatous inflammation, follicular

TF_{1-9} — Follicular trachoma ≥ 5.0% among children ages 1–9 years

TI — Trachomatous inflammation, intense

TIS — Trachoma impact survey

TS — Trachomatous conjunctival scarring

TSS — Trachoma surveillance survey

TT — Trachomatous trichiasis

UTE — Unexpected therapeutic effect

WHO — World Health Organization

Embet Belachew, aged 7, is receiving her dose of azithromycin in the form of powder for oral suspension in North Mecha Woreda, Amhara Region, Ethiopia. An annual dose of azithromycin is offered to everyone in the community as part of the comprehensive SAFE strategy (Surgery, Antibiotics, Facial cleanliness, and Environmental improvement) to end trachoma. Children bear the highest burden of infection, making their inclusion in distribution essential. To maximize patient safety, all children aged 6 months to 7 years are offered a sweet-tasting syrup. Older children and adults are offered tablets. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

Letter from the ITI Team

In 1998, the International Trachoma Initiative (ITI) was formed with a nearly impossible goal: the global elimination of an ancient disease. Over the past 25+ years since, hundreds of highly dedicated people have worked together in partnership to make incredible progress towards this goal. As of October 2024, 21 countries have been validated by WHO as having eliminated trachoma as a public health problem. Through the generous donation of azithromycin, Pfizer Inc. (Pfizer) catalyzed this global program, donating over 1 billion treatments since 1999 and extending their commitment through 2030.

The scale-up of the trachoma elimination program offered us many lessons in the management and distribution of azithromycin, which were reflected in the 2019 *Zithromax® Management Guide.* Since that version was released, many national trachoma programs have entered the 'end game' phase of the program and our community has encountered new and different challenges, with critical changes now being reflected in this updated 2024 version of the Azithromycin Management Guide (AMG).

Together, we have navigated the COVID-19 pandemic, Zithromax® production shortages, insecurity, and civil conflict, and the recognition that our elimination strategies don't always work the same everywhere. Together, we have learned from local experts, adapted our solutions to specific contexts, found ways to reach ALL populations — including the hardest to reach, and demonstrated flexibility and unwavering dedication in our partnership.

In this updated guide, you will note the following changes:

- The use of the more expansive term "azithromycin" (replacing the brand name Zithromax®)
- Updated guidance for managing treatments in implementation units with 'persistent' and 'recrudescent' trachoma
- A discussion of the use of alternative indicators for supporting the determination of trachoma as a public health problem

The guidance in this updated version is presented in two sections: one that provides guidance to program managers, planners, and implementers; and the other for pharmaceutical supply chain managers.

We offer this guide to better support the important work that you do, so that together, we may achieve a world free from trachoma.

— The International Trachoma Initiative Team

Azithromycin Management Guide

A child in Wolaita Sodo, South Ethiopia, receives his dose of azithromycin in powder for oral suspension form under the careful guidance of community drug distributors (CDD). *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

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Two medical professionals in southern Ethiopia remove sutures from a young woman's eyes following trachomatous trichiasis surgery. This procedure is a key part of the SAFE strategy, preventing blindness by correcting in-turned eyelashes that damage the cornea. Women are 1.8 times more likely than men to need this intervention. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

1. Introduction

Intensive efforts are underway to eliminate trachoma as a global public health problem.

The comprehensive "SAFE" strategy, which incorporates surgery to manage trichiasis, antibiotics to address active infection, and facial cleanliness and environmental improvement to prevent the spread of infection, is being implemented in the majority of trachoma endemic countries, with great success to date. Over the past 25 years, strong partnerships have been built and sustained despite challenges, while countries have generated high-quality data that provide a clear understanding of where trachoma interventions are still needed — driving significant progress toward global trachoma elimination.

The International Trachoma Initiative (ITI) was founded in 1998 to help answer the World Health Organization's (WHO) call to eliminate trachoma as a public health problem. ITI provides comprehensive support to national ministries of health and governmental and nongovernmental organizations to eliminate trachoma. ITI has managed the allocation and distribution of the antibiotic, Zithromax® (azithromycin), donated by Pfizer Inc. (Pfizer), to treat active trachoma infections for many years. Additionally, ITI supports program monitoring and evaluation and develops and strengthens partnerships for implementing the SAFE strategy for disease elimination.

To help ensure product needs are more consistently met, Pfizer undertook a careful review of their end-to-end supply chain and distribution network to identify opportunities to improve availability of drugs for donation. As a result of their comprehensive review, Pfizer identified a new manufacturer for azithromycin, which is increasing production capacity to better meet the needs of national trachoma programs.

As a result of adding a new manufacturer, you will notice changes in the product label. The most significant change is that the donated product will now be labeled **"Azithromycin – Donation for ITI only"** instead of **"Zithromax® – Donation for Treatment of Trachoma"**.

With this change, it is important to note that:

- **Azithromycin – Donation for ITI only** is bioequivalent to **Zithromax® – Donation for Treatment of Trachoma** in terms of safety, efficacy, and quality.
- The new donated azithromycin has been approved by the United States Food and Drug Administration.
- The new azithromycin tablets are 250 mg, pink, and come in a 500 count bottle — the same as Zithromax®.
- The package insert is identical to the package insert approved in the United States and does not include a reference to trachoma or a translated version for this reason.
- If your country has a local registration for Zithromax® or azithromycin, the donated product may differ in certain respects from the product registered locally. Donated product is supplied with a product label created specifically for the trachoma program, which enables programs to distinguish between donated azithromycin to treat trachoma and azithromycin used for general health system purposes.
- The newly branded product, **Azithromycin – Donation for ITI only**, began shipping in June 2024.
- Donated Zithromax® may still be in circulation until 2028.

1.1: Trachoma Epidemiology

#1 Trachoma is the **world's leading infectious cause** of blindness.	As of September 2024, an estimated **103 million people** in 39 countries are at risk of trachoma.	An estimated **1.9 million people are blind** or visually impaired due to trachoma.
An estimated **1.5 million people are in need of trichiasis surgery** or management to prevent them from becoming blind.	**Women are** two times **more likely than men to be blinded** by trachoma because of, in part, their roles as the primary caregivers of children.	**Africa is the most trachoma-endemic continent** with people most at risk living in areas with poor access to water and sanitation facilities.

1.2: Purpose of the Azithromycin Management Guide (AMG)

This is a revised version of the 2019 Zithromax® Management Guide that was first developed in 2010.

- This guide is for trachoma program managers and National Trachoma Task Forces in countries participating in the azithromycin donation program.
- The guide will assist programs in the planning, implementation, and evaluation of the antibiotic (the "A") component of the SAFE strategy.
- The AMG builds upon the previous version and incorporates the experiences of national trachoma programs in their distribution of azithromycin.
- The AMG includes updates to reflect new approaches to the elimination of trachoma as a public health problem.
- It refers to other manuals and guides, including from WHO and the preferred practice documents from the International Coalition for Trachoma Control (ICTC). These manuals and guides (see Annex 1) will provide a more comprehensive explanation of the issues and should be used as references.
- This revised AMG reflects changes in the manufacturer of azithromycin.
- The advice and preferred practices for trachoma elimination are constantly evolving. The AMG should be used only as a guide, and cannot take into account all of the aspects of the local context.

Economic Impact of Trachoma

Trachoma negatively impacts the economic well-being of entire families and communities, and can affect an individual at any point in their lifetime.

A woman who becomes visually impaired because of the disease can no longer perform vital activities for her household, such as gathering water and firewood and cooking. To fill this gap, an older daughter may be taken out of school to assume those responsibilities, foregoing her opportunity to break the cycle of poverty with a formal education.

1.3: SAFE Strategy

- The SAFE strategy was adopted by WHO in 1996 and formalized in the World Health Assembly Resolution 51.11 (see Annex 2) in 1998 as the means to achieve elimination of trachoma as a public health problem.
- In 1997, the Alliance for the Global Elimination of Trachoma by the year 2020 (GET2020) was established, bringing together WHO, national trachoma programs, government and nongovernmental partners, academics, and donors.
- Pfizer announced its donation of azithromycin for national trachoma programs in 1998, when it established ITI. Since 2009, ITI has been a program of The Task Force for Global Health, an independent nonprofit organization. ITI allocates the donated drug according to need as recommended by the Trachoma Expert Committee (TEC), an independent body of internationally recognized experts within the trachoma sector.
- The antibiotic donation is to be used in the context of the overall SAFE strategy in all endemic districts.

Trachoma Transmission

- Trachoma generally occurs in poor communities where people live in close proximity and have limited access to water, sanitation, and primary health care.
- Trachoma is spread through contact with discharge from the eyes and nose of an infected person.
- Flies that seek out eyes infected with trachoma can also transmit the disease from person to person.
- The flies that spread trachoma breed in human feces.
- Shared towels, cloths or bedding contaminated with the discharge from the eyes and nose of an infected person could also spread the disease.

Surgery
to treat the blinding stage of the disease

Antibiotics
to clear infection (donated by Pfizer)

Facial cleanliness
and hand hygiene to help reduce transmission

Environmental improvement
for access to water and sanitation

1.4: The Life Cycle of Trachoma

Trachoma is an eye infection caused by the bacterium ***Chlamydia trachomatis***. The bacterium is spread by direct person-to-person contact, shared cloths and towels, and eye-seeking flies. Children aged 1–9 years and women harbor the greatest burden of disease. Repeated infections scar the inner eyelid, eventually causing the eyelid to turn inward. Once the eyelid has inverted, the eyelashes scratch the cornea, leading to irreversible blindness.

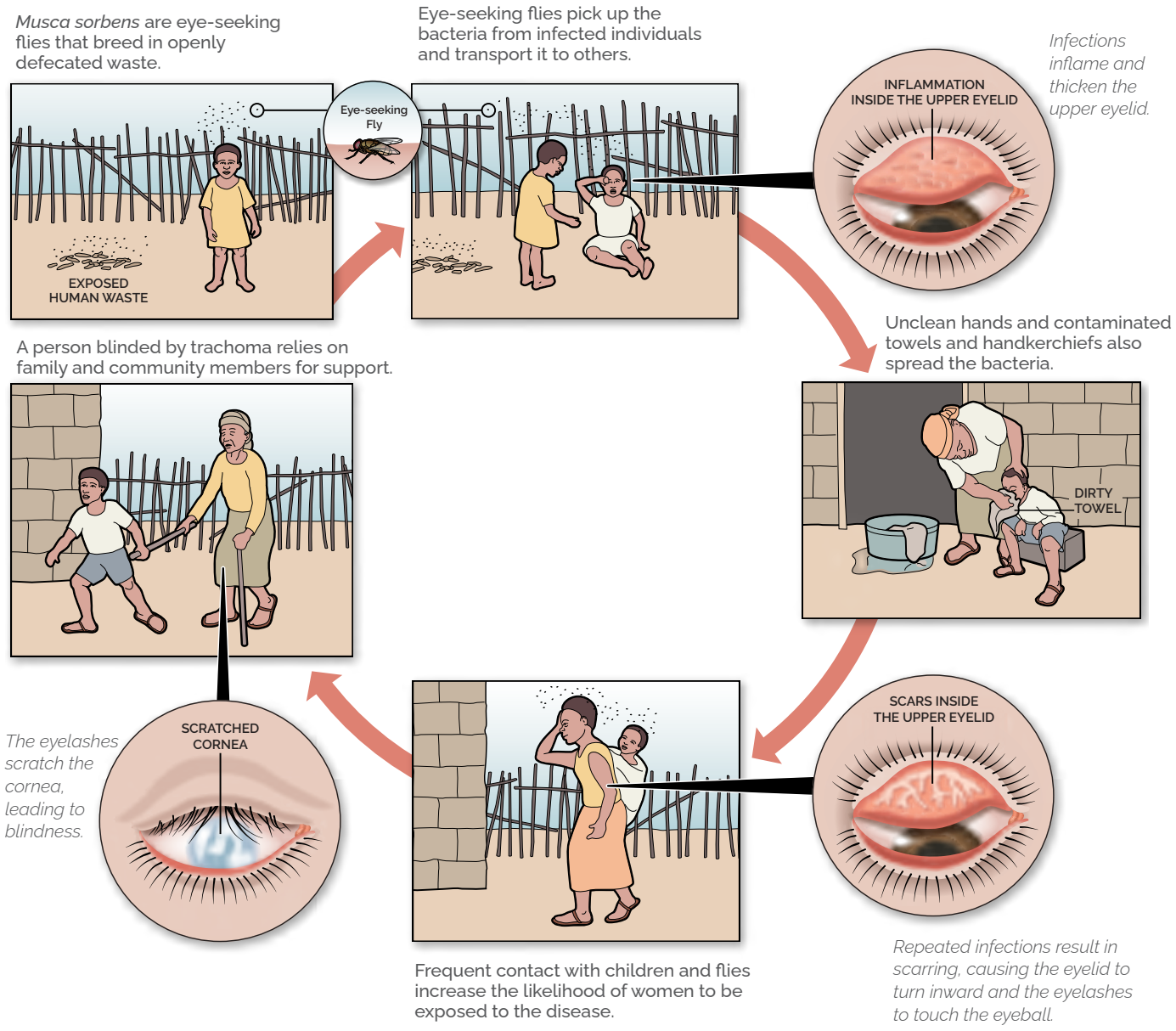


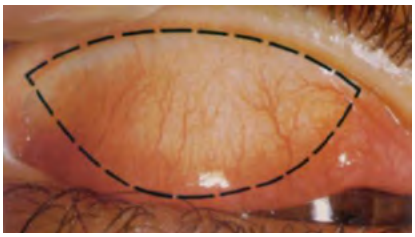
Image Credit: The Carter Center / Graphic by Al Granberg

1.5: Trachoma Grading

Trachoma is usually diagnosed clinically, and individuals are examined for clinical signs through the use of magnifiers (loupes). In the early stages, infection may not present visible signs of the disease. After repeated trachoma infections, the inside of a person's eyelid can become scarred and turn inward, causing the eyelashes to scrape against a person's eye with each blink. This condition is called trachomatous trichiasis (TT), and without immediate management, a person with trichiasis will slowly and painfully become blind. The WHO's grading system for trachoma classifies the disease in five grades.

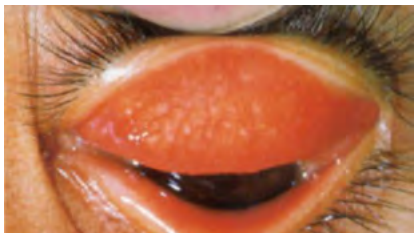
Trachoma Grading Card

- Each eye must be examined and assessed separately.
- Use binocular loupes (x 2.5) and adequate lighting (either daylight or a torch).
- Signs must be clearly seen in order to be considered present.



1. Normal Eyelid

- Normal tarsal conjunctiva (x 2 magnification). The dotted line shows the area to be examined.
- The eyelids and cornea are observed first for inturned eyelashes and any corneal opacity.
- The upper eyelid is then turned over (everted) to examine the conjunctiva over the stiffer part of the upper lid (tarsal conjunctive).
- The normal conjunctiva is pink, smooth, thin and transparent. Over the whole area of the tarsal conjunctiva there are normally large deep-lying blood vessels that run vertically.

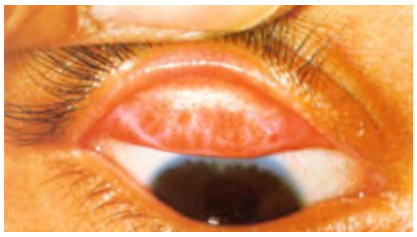


2. Trachomatous Inflammation – Follicular (TF)

- The presence of five or more follicles in the upper tarsal conjunctiva.
- Follicles are round swellings that are paler than the surrounding conjunctiva, appearing white, grey, or yellow. Follicles must be at least 0.5mm in diameter, i.e., at least as large as the dots shown below, to be considered.

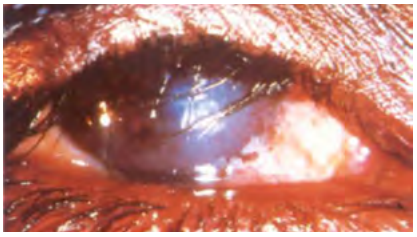
3. Trachomatous Inflammation – Intense (TI)

- Trachomatous Inflammation – follicular and intense (TF + TI).
- Pronounced inflammatory thickening of the tarsal conjunctiva that obscures more than half of the normal deep tarsal vessels.
- The tarsal conjunctiva appears red, rough and thickened. There are usually numerous follicles, which may be partially or totally covered by the thickened conjunctiva.



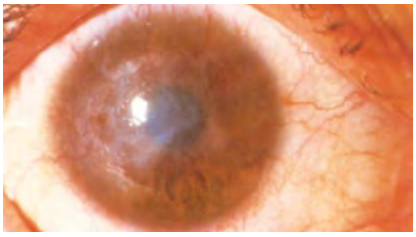
4. Trachomatous Scarring (TS)

- The presence of scarring in the tarsal conjunctiva.
- Scars are easily visible as white lines, bands, or sheets in the tarsal conjunctiva. They are glistening and fibrous in appearance.
- Scarring, especially diffuse fibrosis, may obscure the tarsal blood vessels.



5. Trachomatous Trichiasis (TT)

- At least one eyelash from the upper eyelid touches the eyeball, or evidence of recent epilation of inturned eyelashes from the upper eyelid.



6. Corneal Opacity (CO)

- Easily visible corneal opacity over the pupil.
- The pupil is blurred viewed through the opacity. Such corneal opacities cause significant visual impairment (less than 6/18 or 0.3 vision), and therefore visual acuity should be measured if possible.

- **TF: Give topical treatment (e.g. tetracycline 1%).**
- **TI: Give topical and consider systemic treatment.**
- **TT: Refer for eyelid surgery.**

WORLD HEALTH ORGANIZATION PREVENTION OF BLINDNESS AND DEAFNESS

Support from parts of the WHO Alliance for the Global Elimination of Trachoma is acknowledged.

1.6: *Chlamydia trachomatis (C. trachomatis)* Infection and Serology

To better understand trachoma epidemiology in areas with potential uncertainty around TF diagnosis, especially after multiple rounds of antibiotic MDA, some national programs are incorporating complementary indicators, such as *Chlamydia trachomatis (C. trachomatis)* infection and serology, beyond TF grading. To date, these complementary indicators have most commonly been added to trachoma surveys in two scenarios:

1. Settings in which TF and TT were discordant (i.e., follicular trachoma among children ages 1-9 [TF_{1-9}] ≥ 5% with minimal to no TT among adults) at baseline; and
2. Areas with persistent and recrudescent trachoma (see Section 2.2 – Decision-Making for Azithromycin MDA).

C. trachomatis Infection

C. trachomatis infection is assessed through detection of the bacterium *C. trachomatis* in conjunctival swabs. The samples are analyzed using nucleic acid amplification tests (NAAT) such as polymerase chain reaction (PCR), which amplifies small amounts of a specific DNA sequence that exist in a sample so that it can be better detected. Through this sample collection and analysis, it is possible to estimate the prevalence of *C. trachomatis* infection in a population.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

C. trachomatis Serology

In contrast to measuring the prevalence of current infection, serology measures the prevalence of antibodies. This represents a history of exposure to *C. trachomatis* at any time in the past, which could include an infection that is ongoing at the time of sampling. Antibodies are generated in response to certain proteins from an infectious agent. In the case of ocular *C. trachomatis* infection, the primary protein used in analysis is Pgp3. The presence of these antibodies can be detected from blood (such as a dried blood spot) using one of a number of different immunoassays (multiplex bead assay, ELISA, or lateral flow assay). In areas of high trachoma endemicity, a higher proportion of children overall will be antibody-positive, and the proportions of children who are positive will increase with year of age due to increasing cumulative exposure over time. Conversely, in areas of low transmission, children are rarely if ever infected with ocular *C. trachomatis* resulting in smaller proportions of children being antibody-positive across the age ranges.

Serology can be reported as the prevalence of antibodies to Pgp3 in children (typically 1–5 year-olds), but a more useful indicator is the seroconversion rate. The seroconversion rate is the rate at which susceptible individuals in the population move from an antibody negative status to an antibody positive one (i.e., seroconvert). This number represents the increase in seroprevalence by year of age, which provides an estimate of the force of infection and is a useful estimate of transmission of ocular *C. trachomatis* in a population. When the seroconversion rate reflects a lack of increase in seroprevalence by year of age, it can be used to rule out the cumulative exposure to ocular *C. trachomatis* in children. This is an important measure in the context of trachoma elimination because multiple infections — potentially > 150 in a lifetime — are needed to develop trichiasis. Because antibodies can be present in blood for years after infection is gone, it is important to recognize that these are not diagnostic and provide a separate measurement of transmission than infection.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

These complementary indicators are meant to provide additional information about trachoma transmission and should be analyzed holistically, especially as the global trachoma community awaits official guidance and benchmarks from WHO. As more countries collect complementary indicator data and include infection and serology information as part of their programmatic decision-making, ITI will continue to liaise with national programs, their partners, and experts to ensure that drug allocations are evidence-based and fair.

A newly labeled bottle of azithromycin marked 'Azithromycin - Donation for ITI Only,' distinguishing it from azithromycin used in general health systems and ensuring its dedicated use for trachoma elimination efforts. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

2. Azithromycin Donation Program

2.1: Qualifying for Azithromycin

ITI operates a transparent, evidence-based program for the donation of azithromycin. Any country can apply for azithromycin for use in their trachoma elimination program if the following criteria are met:

- ❑ A population-based prevalence survey shows evidence of at least one trachoma-endemic district in the country.
- ❑ The population-based prevalence survey data are less than 10 years old.
- ❑ The Ministry of Health (MOH) signs a three-year Memorandum of Understanding (MOU) with ITI through The Task Force for Global Health agreeing on how the donated azithromycin should be stored, managed, and distributed.
- ❑ Funding is available to support the antibiotic distribution.
- ❑ There is a plan for the distribution of azithromycin in the context of the SAFE strategy.

2.2: Decision-making for Mass Drug Administration (MDA) with Azithromycin

The treatment schedule is based on district prevalence of TF_{1-9} determined in population-based prevalence surveys:

- ❑ If TF among children 1-9 years old is less than 5.0%, MDA is not required.
- ❑ If TF among children 1-9 years old is between 5.0% and 9.9%, one year of MDA is recommended, followed by an impact survey at least six months following the last MDA.
- ❑ If TF among children 1-9 years old is between 10% and 29.9%, three years of annual MDA is recommended, followed by an impact survey at least six months following the last MDA.
- ❑ If TF among children 1-9 years old is 30% to 49.9%. five years of annual MDA is recommended, followed by an impact survey at least six months following the last MDA.
- ❑ If TF among children 1-9 years old is above 50%, seven years of annual MDA is recommended, followed by an impact survey at least six months following the last MDA.

Once TF among children 1–9 years old drops below 5% in a district, the program should wait two years before conducting a population-based surveillance survey (see page 19). If the surveillance survey shows that the district's TF_{1-9} remains below 5%, then no further MDA in that district is required. If the district-level TF_{1-9} returns as ≥ 5%, then MDA may need to resume.

A country can potentially meet the criteria for trachoma elimination when all three of these criteria are met:

- ❑ Prevalence of TT unknown to the health system of < 0.2% in population aged 15 years and above
- ❑ Prevalence of TF in children aged 1-9 of < 5% in each formerly endemic district
- ❑ Written evidence that the health system can identify and manage incident TT cases

The country can then prepare a dossier documenting the achievement of these elimination targets. The standard operating procedures for submitting the dossier and related templates are available on the WHO's publication resource webpage for trachoma. Contact your WHO country office for the latest version of the template.

In a minority of districts around the world, the delivery of the standard SAFE strategy has not resulted in the expected progress towards trachoma elimination. In these areas, alternative MDA and monitoring strategies may be warranted to achieve elimination targets. Following the 2021 WHO informal consultation on endgame challenges hosted by ITI and deliberations by TEC in subsequent years, ITI and TEC invite countries and partners to request azithromycin for modified strategies. Four categories of districts are eligible to apply for a modified approach:

1. Districts with **persistent trachoma**, where there have been two or more trachoma impact surveys (TIS) in which the prevalence of TF_{1-9} has never been below 5% (and the current TF_{1-9} remains ≥ 5%)
2. Districts with **recrudescent trachoma**, where the result of at least one trachoma surveillance survey (TSS) has come back with a TF_{1-9} ≥ 5% (and no subsequent TSS has achieved a TF_{1-9} < 5%)
3. Districts with **high TF prevalence**, where the current TF_{1-9} prevalence is ≥ 30%
4. Districts where trachoma impact surveys have been **delayed for more than 2.5 years since MDA** and the new TIS results indicate TF above threshold (even if the district did not previously qualify as 'persistent' or 'recrudescent')

Requests for azithromycin for modified MDA strategies are subject to the availability of azithromycin. In those districts that meet the criteria outlined above, programs may choose to request to modify their trachoma program implementation using donated azithromycin in the following ways:

MDA Strategies:

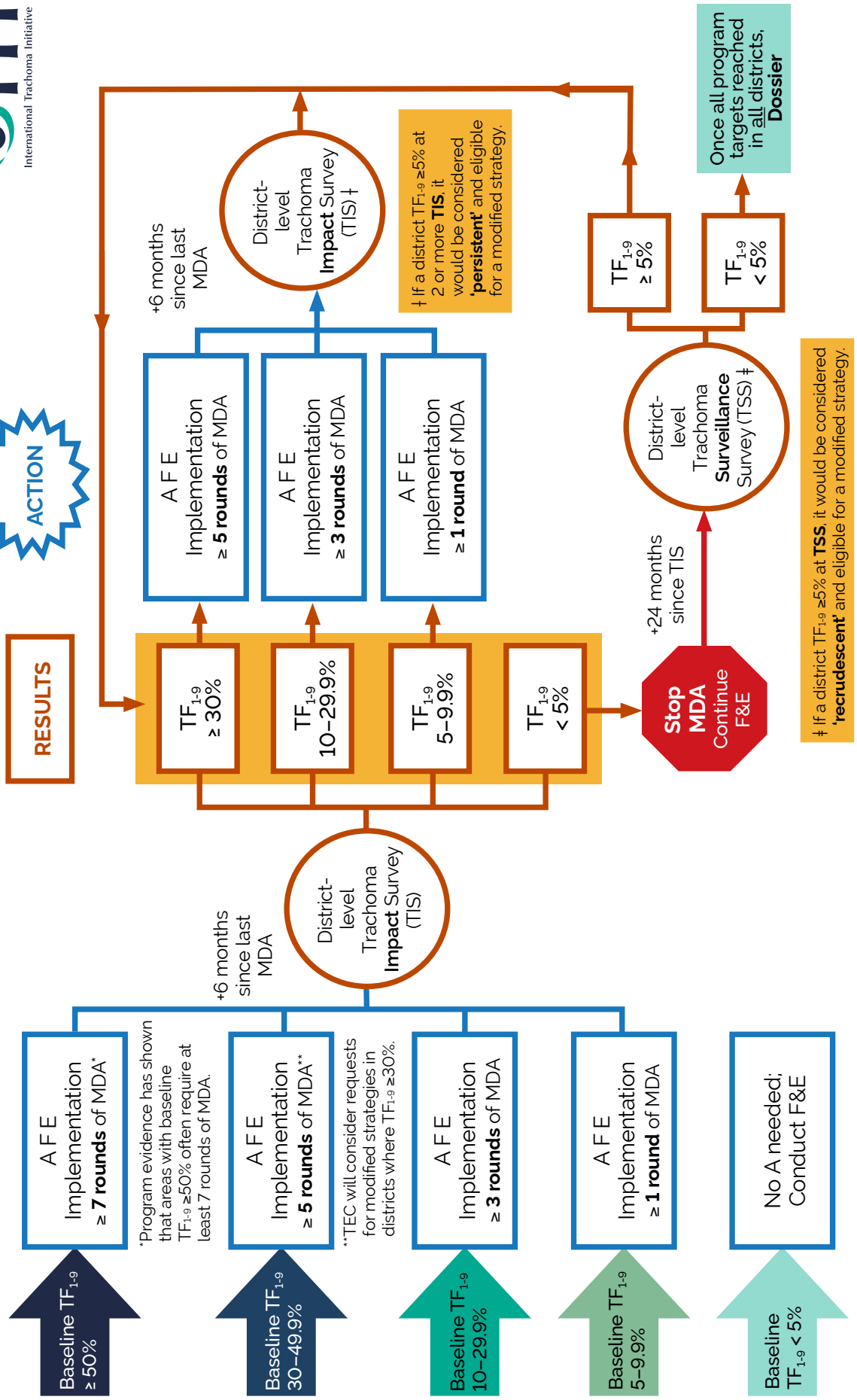
1. **Increased frequency of MDA.** Programs can conduct more-frequent-than-annual (MFTA) MDA. The additional treatment rounds can be targeted (e.g., to children only) or provided to the entire community. The timing is flexible (e.g., biannual MDA can be conducted on months 0 and 1, months 0 and 4, months 0 and 6, or any schedule that makes programmatic sense). Likewise, three rounds could be conducted in any timing combination that works for the program. The sum of the MFTA MDAs conducted in a year are considered one round (e.g., a district with TF_{1-9} 10-29% conducting biannual MDA for three years would complete six total treatments in three annual rounds before a TIS is required). It is important that the implementation plan leaves no one behind, anticipates high coverage MDA, and is paired with strong F&E.
2. **Increased number of MDA rounds**. For example, a program may choose to implement two-to-three years of AFE in a district with TF_{1-9} 5-9% instead of the standard one year before conducting their next TIS.

Programs may elect to adopt enhanced monitoring strategies instead of, or in combination with, modified MDA strategies.

Monitoring Strategies:

1. **Enhanced investigation.** Programs are encouraged to conduct enhanced investigations to better understand factors contributing to persistence, recrudescence, or high levels of TF so that interventions can be tailored to the problem. This may include a deep dive into existing data on coverage, infection distribution, WASH gaps, etc. Geostatistical analyses may prove helpful.
2. **Program enhancement.** Programs would put in place measures and strategies based on the enhanced investigation to ensure quality and consistent coverage that reaches all populations and subgroups (e.g., migratory populations).
3. **Infection and serological data.** Programs may elect to collect age-stratified infection and serological data to better assess whether the TF prevalence is indicative of ongoing transmission at the level of a public health problem. Further work is required to guide the collection and use of these data in programs.

Diagram on Decision Making for the Antibiotic Treatment of Trachoma



Updated November 2024

4. **Adapted TIS.** Geostatistical or adaptive survey designs could be used to provide a reliable and quick indication that TF is above threshold and better assess TF in special populations. These adapted surveys may also include the collection of infection and serological data (thresholds will need to be established). Further work is required to define survey design.
5. **Adapted evaluation unit.** The evaluation unit could be adapted to take into account migratory populations, ensuring the entire group is included, even across country borders.
6. **Remain in surveillance ("wait and see").** Programs could continue F&E without MDA for a period of time, expecting that the TF_{1-9} will regress to < 5%, especially if surrounding districts have a prevalence of TF_{1-9} < 5%. This strategy would be most appropriate for recrudescent districts (those with a prevalence of TF_{1-9} ≥ 5% at TSS).

If your program has districts that fit these criteria and you would like to apply for azithromycin for a modified strategy, your ITI program liaison will work closely with your program to develop supplemental application materials.

2.3: Application Process

ITI has an annual application process for all countries applying for azithromycin. The annual process determines azithromycin needs for the upcoming year. ITI generally requires a year lead time to ensure the production and supply meet the country's needs. ITI provides TEC with detailed information on the country's trachoma elimination efforts to inform evidence-based, consistent, and transparent allocations of drug. TEC is an independent body of internationally recognized experts that meets twice annually to review country applications for donations of azithromycin and provide invaluable advice to ITI on strategic, technical, and operational issues.

Photo credit: International Trachoma Initiative

The application requests information on program details, including:

- ❑ Updates on trachoma prevalence data, which should not be more than 10 years old
- ❑ Current population estimate, by district
- ❑ Treatment distribution data from the previous year
- ❑ District-level MDA and survey plans for the upcoming year, including any modified MDA and monitoring strategies
- ❑ Requests for donated azithromycin for use in TT surgeries and/or research
- ❑ Commitment to full implementation of the SAFE strategy
- ❑ Funding and implementation partners (government or nongovernmental) for each district receiving azithromycin

The data collected in this process allow ITI and TEC to:

- ❑ Make evidence-based decisions on azithromycin allocations
- ❑ Plan for on-time shipments of azithromycin to countries
- ❑ Forecast future country-specific azithromycin requirements
- ❑ Estimate global azithromycin demand to support global trachoma elimination efforts
- ❑ Coordinate five-year supply planning with Pfizer to ensure consistent production and availability
- ❑ Identify gaps for full SAFE implementation

Azithromycin Application Process and Timeline

Month	Activity
January	ITI sends azithromycin application to national trachoma program for the following year
March	National trachoma program submits application to ITI
March to June	Consultation among MOH, ITI staff, and TEC liaison
June to November	TEC makes azithromycin allocation decisions ITI sends MOH notification of TEC decisions and either enters into a new MOU or updates the current three-year MOU with an addendum
Prior to shipment	Countries report to ITI on remaining inventory from the prior year
1–2 months prior to MDA	ITI ships azithromycin to countries (timing of shipment depends upon country's MDA schedule)
March (following year)	Country reports to ITI on treatments distributed during the past year in the WHO/ITI Trachoma Elimination Monitoring Form (TEMF) which is combined with the azithromycin application

Although TEC reviews applications on a set timeline twice per year, under certain circumstances ITI and TEC accept requests throughout the year, as new data or funding become available.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

District-Level Azithromycin Donation Criteria

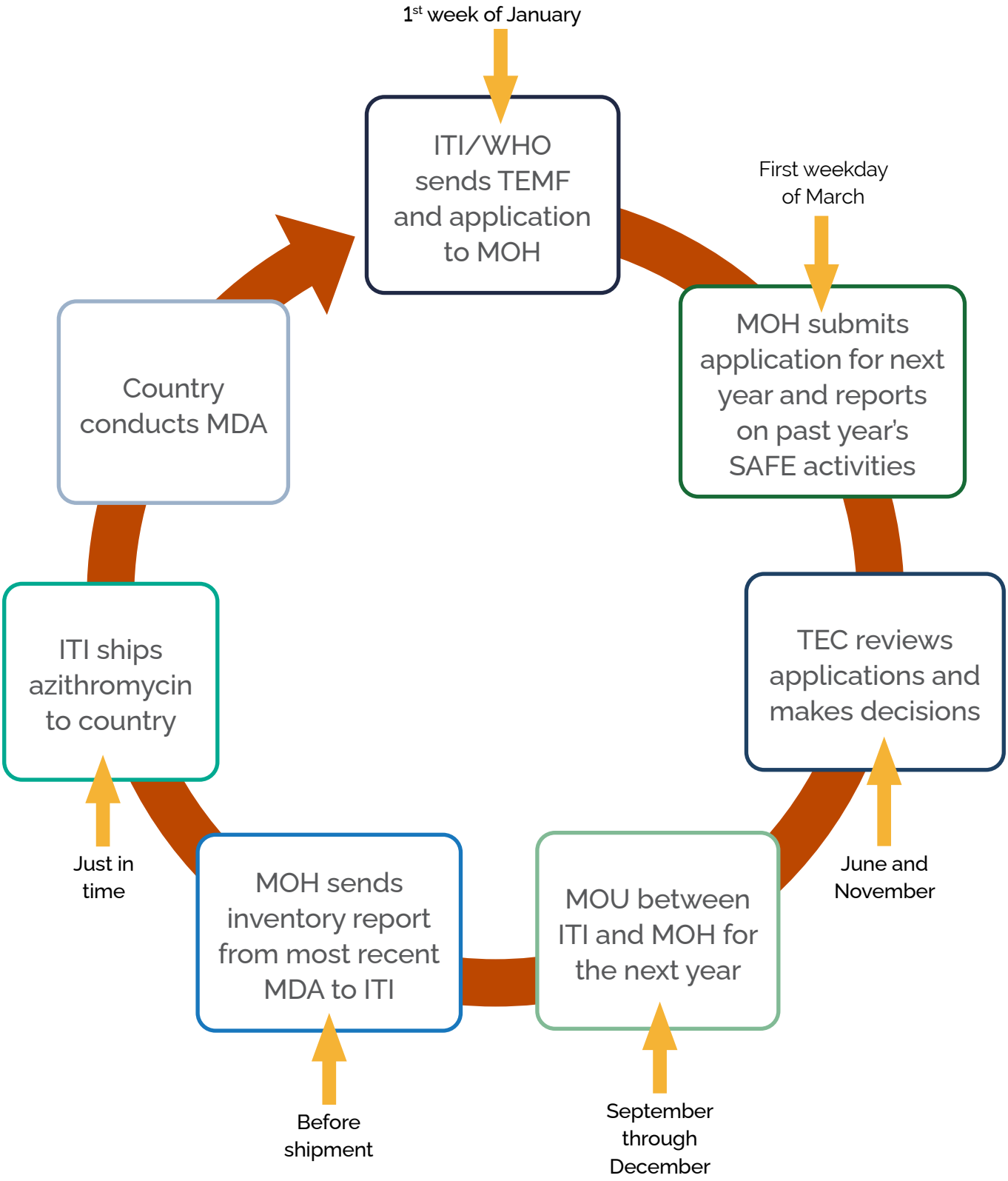
- TF prevalence among children ages 1 to 9 years ≥ 5% and/or *C. trachomatis* infection and/or Pgp3 serology data suggest ongoing transmission as a public health problem
- Funding available to support MDA
- Commitment to implementing facial cleanliness strategies and environmental improvements in all trachoma-endemic districts, and surgeries as needed

2.4: Summary

ITI is here to help you access the azithromycin your country needs to eliminate trachoma as a public health problem.

- ITI exists to ensure you receive the right amount of azithromycin at the time you need it for MDA.
- The azithromycin application document contains two parts:
  - The Alliance for GET2020 Trachoma Elimination Monitoring Form (TEMF) for reporting on the previous year's activities
  - The azithromycin application for the upcoming year
- The TEMF is for activities that occurred during the previous year (i.e., the TEMF submitted in 2025 is for activities that occurred in 2024).
- Azithromycin applications are for the following year (i.e., an application submitted in 2025 is for azithromycin needed in 2026).
- Countries must submit a request each year in their application for every district in which they plan to treat.
- Each district where a donation is requested must satisfy the donation criteria during every application cycle.
- Applications should be prepared by the National Program Coordinator in close collaboration with the National Trachoma Task Force. ITI assigns each country a program liaison and a supply chain liaison, who work closely with the national program to ensure that the national program's needs are addressed.
- With the information that the national program provides, the ITI program liaison will advocate for your country in drug allocation discussions with TEC members.
- Both the TEMF and the azithromycin application are pre-populated by ITI with projected district population figures. The national program should review and make any corrections on the population tab of the joint TEMF/azithromycin application document.
- ITI is always trying to make the azithromycin application process easier, so please check that the instructions included in the application package have not changed since the previous year. Do not hesitate to contact your ITI program liaison if you have any questions.

2.5: Azithromycin Application Timeline



2.6: Application Review

The annual azithromycin application is reviewed by TEC when they meet twice annually, in June and in November. TEC makes district-level recommendations to ITI based on the data presented for each district:

- ❏ Trachoma prevalence collected within the last 10 years
- ❏ Population size estimates
- ❏ Number of rounds of MDA already conducted
- ❏ Coverage achieved for each round
- ❏ Schedule for population-based prevalence surveys (baseline, impact, and surveillance)
- ❏ Availability of financial and implementation support for MDA

For countries requesting drug for modified strategies, TEC will review:

- ❏ Survey history
- ❏ Current prevalence for target district
- ❏ Country's proposed plan for modified strategy
- ❏ Availability of financial and implementation support for modified strategy

Depending on the data presented for each district, TEC will apply one of the following decisions to each district request:

1 Approve Azithromycin
to be allocated for the upcoming year.

2 Approve Azithromycin
with contingency:

A. Pending confirmation of available funding, and/or

B. Pending results from population-based prevalence surveys, and/or

C. Pending resolution of a special situation, either

i. Outside the control of the national program (e.g., conflict, disease outbreak, natural disaster).

ii. Requiring intervention by the national program (e.g., azithromycin theft, unauthorized use of azithromycin outside the trachoma program, problems with national supply chain, lack of compliance with MOU).

3 Does not meet criteria:
For trachoma endemic districts that do not meet the criteria for donation (e.g., no up-to-date prevalence data available, prevalence of TF_{1-9} < 5%, or other concerns regarding ability to scale up), the ITI program liaison will work closely with the country to ensure that the district will receive an azithromycin donation in a future application, if warranted.

Once the application for azithromycin for the upcoming year has been reviewed by TEC, ITI will communicate the decisions to the MOH and their partners.

The MOU contains three key components:

- The main agreement detailing the legal obligations to which both ITI and the MOH commit in regard to the donation and management of azithromycin
- An addendum detailing the azithromycin allocation decisions for the upcoming year
- An addendum about what is necessary to report to Pfizer regarding azithromycin product quality concerns, at-risk scenarios, adverse events, and unexpected therapeutic effects and how to report them

2.7: Memorandum of Understanding (MOU)

- An MOU is signed by ITI and the MOH for a period of three years. In subsequent years, an addendum to the existing three-year MOU will then be sent to the MOH that details the allocation of the drug for that year. The language of the MOU is standardized across all recipient countries.
- Once the treatment for any year has been allocated, ITI will take the necessary steps to ensure the drug arrives in the country prior to the scheduled MDA.
- Failure to comply with the terms set forth in the MOU may result in suspension of the azithromycin donation. For example, administration of azithromycin for unapproved uses or in areas not approved by TEC will jeopardize the country's drug donation in the future.

2.8: Receiving Azithromycin

- ITI's Supply Chain Team will request the country to submit MDA distribution and inventory reports immediately following MDA and may request an update no less than six weeks prior to receiving the next shipment.
- ITI's Supply Chain Team will work with the national program to:
  - Re-confirm shipping documentation and importation requirements;
  - Determine timing of the shipment; and
  - If requested or as needed, conduct periodic supply chain assessments in collaboration with the national program to address any systemic issues related to azithromycin management.
- For details on supply chain management, please see Part II of this guide entitled **"Azithromycin Supply Chain Management Guide."**

2.9: Annual Reporting Process

Countries are required to submit two annual reports:

1. Trachoma Elimination Monitoring Form (TEMF)
   - National programs submit annual reports to WHO and ITI on the distribution of azithromycin via the TEMF, which is included with the azithromycin application and due to ITI in March each year.
   - The TEMF and annual azithromycin application have been combined into a single process which includes pre-populated data fields to reduce the administrative burden on national programs. Global TEMF data are compiled and presented at the annual Alliance for GET2020 meeting and in the WHO Weekly Epidemiological Record.
2. Inventory report
   - National programs must report their post-MDA inventory prior to receiving their next azithromycin shipment. A standardized reporting form is used to facilitate this and will be provided by the Supply Chain Team.

Meseret Mitiku, a community drug distributor (CDD), prepares azithromycin powder for oral suspension (POS) during a mass drug administration at a school in Wolaita Sodo, Ethiopia. *Photo Credit: Brent Stirton/ Getty Images for the International Trachoma Initiative*

3. Mass Drug Administration (MDA) Strategy

The key strategy for the distribution of azithromycin is through MDA. This section will introduce a number of critical aspects for azithromycin MDA. More in-depth information on azithromycin MDA is available on the ICTC website: www.trachomacoalition.org.

3.1: Donated Azithromycin for Trachoma

Azithromycin is presented in two forms: powder for oral suspension (POS) and 250mg tablets.

Powder for Oral Suspension (POS):

POS is an age-appropriate formulation designed to reduce the risk of choking.

- When reconstituted with water, one bottle of POS contains 1,200mg in 30ml (200mg/5ml).
- The powder is white and has a pleasant fruit taste.
- Three dosing cups are provided with each bottle of POS.
- Lot numbers (also called batch numbers) and expiry dates appear on each bottle. The POS is given an expiry of 24 months after manufacture (five days after reconstitution). Azithromycin expires on the last day of the month indicated on the bottle.

Tablets:

- One bottle contains 500 tablets, 250mg each.
- The tablets are oval and bright pink.
- Zithromax® tablets will have **"Pfizer"** stamped on one side and **"ZTM 250"** on the other. Azithromycin tablets will have an imprint code **"L"** stamped on one side and **"590"** stamped on the other.
- Lot numbers (also called batch numbers) and expiry dates appear on each bottle. Zithromax® tablets are given an expiry of 48 months after manufacture (36 months after opening). Azithromycin tablets are given an expiry of 24 months after manufacture. Additional stability testing to confirm a longer shelf life is currently underway. All Zithromax® and azithromycin tablets expire on the last day of the month indicated on the bottle.

For both POS and tablets, the bottle labels are a unique and distinctive purple, with writing in English and in French. The Zithromax® label states **"Zithromax® – Donation for treatment of trachoma only"** and the azithromycin label states **"Azithromycin – Donation for ITI only."** No other packaging is used for donated azithromycin.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

Zithromax® label (to be removed from circulation by 2028)

New azithromycin label

3.2: Population Eligible for Azithromycin

All individuals older than six months in trachoma-endemic communities are offered a single oral dose of azithromycin. The treatment should be directly observed by the distributor.

Powder for Oral Suspension (POS):

- All children over 6 months of age and under 120 centimeters should be offered azithromycin reconstituted POS, at a dose determined by height (see figure on page 32).
- All children over 6 months of age and under the age of 7 years (6–84 months), even if taller than 120 centimeters, should be offered azithromycin POS at a dose determined by height.

Note: Any child of any age whose parent or guardian is concerned about the child's ability to swallow a tablet should be offered POS.

Photo credit: Steven Wade Adams for Pfizer

Tablets:

- Individuals over 120 centimeters AND at least 7 years of age (older than 84 months) up to 15 years of age should be offered azithromycin tablets. The dose will be either 3 or 4 tablets, determined by height (see figure on page 32).
- Individuals 15 years and older should be offered a full adult dose of 4 tablets of azithromycin, regardless of height.
- **Note: Any individual of any age who may have difficulties swallowing a tablet should be offered POS.**
- Pregnant women, according to research and current medical practice, may safely take azithromycin. If they decline, they should be offered tetracycline eye ointment (TEO). Recent studies have examined the effects of azithromycin in pregnancy. Two multicountry randomized trials have found that azithromycin reduced the risk of maternal sepsis or death in women giving birth but had little effect on newborn sepsis or mortality. Ongoing research continues to investigate its potential benefits for preventing stillbirths and improving infant outcomes in high-mortality settings.
  - Azithromycin to prevent sepsis or death in women planning a vaginal birth (New England Journal of Medicine)
  - Effect of Intrapartum Azithromycin vs Placebo on Neonatal Sepsis and Death (JAMA)
  - Antenatal, intrapartum and infant azithromycin to prevent stillbirths and infant deaths (ongoing) (BMJ Open)

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

3.3: Exclusion Criteria

- Children under six months of age are currently excluded from azithromycin MDA. They should be offered TEO, which is not provided by ITI.

Summary of Trachoma MDA Target Groups

MDA Target Group	Formulation
Children aged 0 to < 6 months	Tetracycline eye ointment (TEO)
All children ≥ 6 months to < 7 years Anyone under 120 cm Anyone with difficulties swallowing tablets or uncomfortable taking tablets	Powder for oral suspension (POS; dosage according to height)
Individuals taller than 120 cm Individuals ≥ 7 years to < 15 years	3–4 tablets (dosage according to height)
Individuals 15 years and older	Adult dose of 4 tablets

3.4: Optimal Coverage

- Population coverage is the number of people treated (with either azithromycin or TEO) divided by the total number of residents of the endemic district.
- Note that the program should plan for the actual population residing in the district. Programs may elect to use population data sources outside official census data projections such as health district data, epidemiological data, United Nations High Commissioner for Refugees and/or International Organization for Migration population data, and pre-MDA census.
- In addition to the resident population, the national program should consider the needs of often overlooked population groups when planning, including internally displaced persons, refugees, pastoralists, mobile and migratory communities, indigenous populations, and migrant workers.
- If the national program is interested in treating internally-displaced persons and/or refugees with donated azithromycin, please see Annex 3 for a flowchart for decision-making.

This is a safe administration. The child is calm and controlling the administration himself at a Mass Drug Administration (MDA) in Malawi.
Photo credit: Billy Weeks for the International Trachoma Initiative

3.5: Treating Children

The treatment of children with azithromycin requires caution to avoid choking. The following points need to be incorporated into the training of distributors and supervisors.

- No child should ever be forced to take azithromycin (neither tablets nor POS).
- Distributors must directly observe treatment to ensure that each individual takes the correct dose for him or her. Under no circumstances should individuals be allowed to administer azithromycin to themselves or others without being directly observed by the distributor.
- Distribution sites can be intimidating for younger children. If the young child is anxious or uncooperative, the parent or guardian is the correct person to administer azithromycin POS to reduce the child's anxiety. All drug administration should take place within sight of the distribution team.
- If the young child is uncooperative or anxious, the distributor should instruct the parent to take the child to a quieter location, **within view of the distributor**, to calmly administer the POS. Uncooperative children should never be given tablets.
- While administering azithromycin to a child, NEVER hold the child's nose closed, shake the child, or push the head backwards to force the child to swallow.
- When administering tablets, have the child (or anyone with difficulty swallowing), take one tablet at a time.
- If the child resists, the distributor should register the child as having refused and move on to the next person in line. Azithromycin is a public health program; not treating a few individual children will not undermine the overall success of the program. It is not worth risking a serious adverse event (SAE).
- ***Even if the child is older than 7 years of age and tall enough to be given a tablet, if there is any concern that the child may have trouble swallowing the tablet, POS should be provided.***

3.6: Training Distributors

Different countries use different types of health workers to distribute azithromycin. Many use community volunteers while other countries utilize staff from the MOH system. Training the distributors is important to ensure the drug is safely and efficiently distributed to the right people at the right time using the correct dosage.

- The distribution teams should be trained to perform the following tasks, through role play and hands-on practice:
  - ❑ Prepare and educate communities about trachoma, SAFE, and particularly, azithromycin treatment
  - ❑ Correctly use a height-dosing pole or tape to determine dosing for both POS and tablets
  - ❑ Ensure that safe drinking water is available in sufficient quantities for both reconstituting POS and swallowing tablets
  - ❑ Correctly remove the POS child-safe bottle caps, reconstitute with potable water, and pour the correct amount according to height into the measuring cup
  - ❑ Assess when it is appropriate to administer POS instead of tablets in accordance with the guidance provided in this manual
  - ❑ In the event that a child is anxious or uncooperative, provide the reconstituted POS to the mother or guardian of the child to safely administer the correct dose within view of the health worker
  - ❑ Directly observe treatment with azithromycin POS and tablets
  - ❑ Apply TEO and demonstrate to parents or guardians how to do so twice a day for six weeks
  - ❑ Keep accurate records of distribution using the forms or registers provided by the national program
  - ❑ Monitor and report on SAEs according to national guidelines (see "Reporting Process for Adverse Events" on page 36 for more details)
- As training is usually done in a cascade fashion, supervision is important at each level of the cascade to ensure that the correct information is consistently communicated.
- The training should be conducted for both new and experienced distributors prior to each MDA.

A training manual on MDA supervision may be found on the ICTC web page: www.trachomacoalition.org.

Dose Poles and Their Use

To use the height-dosing stick, the person is asked to stand erect without shoes on a flat floor. The stick is placed vertically against their back, with the "ground" end touching the floor. The horizontal level at the top of the individual's head indicates the number of azithromycin tablets or POS dose to be dispensed. Adults or children with disorders that prevent full extension should be given the same dose as someone of similar age and build.

Note these guidelines:

- ❑ Make sure that the stick is vertical, not leaning to one side
- ❑ Record in the register the number of tablets or amount of POS to be given
- ❑ From time to time, check the stick for bending or warping

If using a paper tape rather than a wooden stick, the tape should be fixed to a wall and the person can then stand next to the wall. Do not attempt to use a loose tape on its own as a measuring device.

Height- and Age-Based Dosing for Azithromycin POS and Tablets

September 2024

International Trachoma Initiative

Infants under 6 months : TEO
(tetracycline eye ointment)

POS
(Powder for Oral Suspension)

Height (cm)	Dosing (ml)
> 138	25 ml
> 130-138	19 ml
> 122-130	16 ml
> 110-122	14 ml
> 98-110	12 ml
> 87-98	10 ml
> 76-87	8 ml
> 65-76	6 ml
> 54-65	4 ml
> 50-54	2 ml

Children ≥ 6 months and < 7 years receiving POS*

Tablets
Height (cm)

> 138

120 - 138

Children ≥ 7 years and < 15 years receiving tablets

≥ 15 years: 4 tablets

Infant | Child | Adolescent | Adult

*Note: Even if the individual is at least 7 years old and tall enough to be given a tablet, if there is any concern that he/she may have trouble swallowing a tablet, POS should be provided.

Azithromycin Dosing Guidelines

September 2024

International Trachoma Initiative

GOAL

ZERO SERIOUS ADVERSE EVENTS DUE TO CHOKING

GOAL

BETTER MANAGING TREATMENTS TO CHILDREN

DOSING BY POPULATION GROUP FOR TRACHOMA MDAs	
MDA Target group	**Formulation**
Children aged 0 to < 6 months	Tetracycline Eye Ointment (TEO)
Children aged ≥ 6 months to < 7 years (regardless of height) Individuals under 120 cm (regardless of age) Individuals with difficulties swallowing tablets or uncomfortable taking tablets	Powder for Oral Suspension (POS) dosed according to height
Individuals taller than 120 cm **and** between the ages of 7 and < 15 years	Tablets dosed according to height
Individuals 15 years and older	Dose of 4 tablets

TREATING CHILDREN WITH AZITHROMYCIN
No child should ever be forced to take azithromycin.
Distribution sites can be intimidating for children. If the child is uncooperative or anxious, the parent or guardian is the correct person to administer azithromycin to the child to reduce the child's anxiety.
If the child is uncooperative or anxious, the distributor should instruct the parent to take the child to a quieter location to calmly administer the dose, within view of the distributor.
While administering azithromycin to a child, NEVER hold the child's nose closed, shake the child, or force the head backwards to force the child to swallow.
If the child resists, the distributor should register the child as having refused and move on to the next person in line.
Even if the child is at least 7 years of age and tall enough to be given a tablet, if there is any concern that the child may have trouble swallowing the tablet, POS should be provided.

Photo credit: Sumon Ray for the International Trachoma Initiative

Opening a POS Bottle and Mixing the Suspension

- Before opening the bottle, shake it firmly to loosen the azithromycin powder.
- The bottles are equipped with special squeeze-and-turn safety caps. To open, squeeze opposite sides of the bottle cap and, while still squeezing, turn the cap while holding the bottle firmly in the other hand.
- Mix the powder first with 5ml of potable water, replace the cap and shake. Then add an additional 10ml of water. The 15ml of water plus the azithromycin powder will make a total of 30ml of POS.
- The date of reconstitution should be written on the label of any bottle of suspension not finished on the day it is reconstituted, and such bottles must be used before new ones are prepared for the next day.
- POS should be used within five days of reconstitution. It is important to only reconstitute as much POS as is needed to avoid expiration.

Tetracycline Eye Ointment (TEO)

Currently, TEO is offered to infants less than 6 months old. TEO is not provided by the International Trachoma Initiative. The following guidance is for 1% tetracycline for ophthalmic use.

- Two tubes of TEO should be provided for each patient.
- The drug distributor should open one of the tubes and demonstrate the application of TEO to the mother or caregiver.
- The infant should be propped in the crook of the caregiver's arm so that they are at an angle and not lying down.
- Gently pull the lower lid from the surface of the eye by placing a finger against the lid, below the lash line.
- Gently squeeze a continuous, single line of ointment behind the lower lid from one side to the other.
- Release the lid so it closes, trapping the ointment behind the lid.
- Repeat for the other eye. The mother or caregiver should be instructed to repeat this twice a day until both tubes are finished.

Compliance with the TEO treatment is typically poor. Administration guidelines should be emphasized during distribution.

3.7: Safety of Azithromycin

- Azithromycin is well tolerated with a very low incidence of serious side effects.
- Communities receiving MDA should be informed in advance that some people will experience mild reactions such as nausea, abdominal discomfort, and diarrhea.
- Families should be encouraged to eat a meal prior to treatment, as this helps reduce nausea.
- Individuals who experience mild side effects should be reassured that in spite of their symptoms they should take azithromycin in subsequent treatment rounds.

Safety reporting requirements are outlined in the MOU and must be followed. National programs should have a mechanism in place in advance of the distribution to ensure immediate reporting of any of the following concerns:

- **Product quality complaint (PQC):** any written or oral expression of dissatisfaction relative to the physical properties, condition, labeling, potency and/or packaging of a product.
  - Examples include:
    - Labels peeling off
    - Ink on labels rubbing off, inhibiting the ability to read important information such as drug name, expiry date, lot number
    - Discoloration (e.g., yellowing) of POS
    - Caking of POS making it difficult to mix when shaking with water
- **Adverse event (AE):** any untoward medical occurrence following drug administration. The event need not necessarily have a causal relationship with the treatment or usage. Please refer to your most recent MOU for the necessary information to comply with reporting requirements.

A mother administering azithromycin Powder for Oral Suspension (POS) to her child during a Mass Drug Administration (MDA) in Zambia. *Photo credit: Sumon Ray for the International Trachoma Initiative*

- **Serious adverse event (SAE):** leads to death, hospitalization, disability, or harm to a fetus.
- **At Risk Scenario (ARS):** circumstances that may increase the consumer's risk of developing AEs. These circumstances include medication errors, overdose, and misuse.
- **Unexpected therapeutic effect (UTE):** a beneficial therapeutic effect from a product aside from the use for which it had been given.

Please see Annex 4 for additional information on safety reporting requirements.

Photo credit Brent Stirton/Getty Images for the International Trachoma Initiative

3.8: Reporting Process for Adverse Events (AEs)

- ❑ The MOH shall report all potential AEs, ARSs, UTEs, and PQCs via the Pfizer-directed reporting mechanism within one business day, or three calendar days, whichever is shorter (immediately, in the case of death or a life-threatening AE).
- ❑ Reporting responsibilities are the same for all AEs, irrespective of the seriousness of the event or whether or not it was caused by the product.
- ❑ All ARSs, UTEs, and PQCs should be reported, whether or not there is an associated AE.
- ❑ AEs should be reported to the Pfizer contacts identified in each country's MOU, which is updated annually in writing by ITI.
- ❑ Distributors and community leaders should be instructed what to do and who to contact if they encounter SAEs during or following the MDA.
- ❑ A designated person should be at the national level to manage reports and ensure Pfizer is notified accordingly.
- ❑ If any SAEs occur, community-directed distribution team members should ensure that the affected person visits a nearby health institution for immediate care.

Please refer to "Safety in administering medicines for neglected tropical diseases" on the WHO website for more in-depth information on SAEs for Neglected Tropical Diseases (NTDs).

Photo credit: Mark Tuschman for the International Trachoma Initiative

3.9: Community Awareness

Program staff should educate the community about trachoma. In addition to locally-determined azithromycin-related messages, the community should be informed about the following, in local languages:

- ❑ Trachoma prevention and blindness from trachoma
- ❑ The reason for treatment with azithromycin
- ❑ Azithromycin is a very safe drug to take
- ❑ Minor side effects of taking azithromycin are nausea and diarrhea, which can be avoided by not taking the drug on an empty stomach (see **Section 3.7 –Safety of Azithromycin**)
- ❑ The precise location and dates of treatment
- ❑ Azithromycin is provided free of charge
- ❑ Face washing and the use of latrines are very important
- ❑ Anyone in the community with eyelashes touching the eye should seek treatment for trichiasis

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

3.10: Dealing with Rumors and Refusals

Experience has shown that adverse events or false rumors about the purpose of the MDA may result in individuals or entire communities declining to participate in MDA. The success of eliminating trachoma depends on the participation of communities. Steps to manage individual or community refusal should be taken as quickly as possible. To help prevent rumors and misperceptions, consider the following practices:

- Be proactive in implementing ongoing activities and increasing communication in advance of the MDA to prevent and limit rumors and reduce concerns about adverse events.
- Build ongoing relationships with communities (religious, social, media) and involve community leaders and stakeholders in planning and implementing health activities.
- Make communication and social mobilization a continuous activity. Mobilization should be based on the understanding of the situation and should specifically target the roots of the concerns the communities have.
- Disseminate consistent messages to the community and take the time to address rumors, as doing so will benefit the MDA campaign now and in the future.

If rumors persist and communities are reluctant to participate in MDA:

- Analyze the situation by conducting informal discussions and interviews with leaders and influential community members to understand the reasons for not participating.
- If the reluctance is widespread, formal qualitative research may be needed to more effectively tailor mobilization messages to the community's concerns.

Please remember: An individual should never be forced to take a dose of azithromycin. If an individual does not wish to take azithromycin, their right to refuse the drug must always be acknowledged and respected.

Photo credit: Sumon Ray for the International Trachoma Initiative

3.11: Supportive Supervision

Supervision of the azithromycin distributors is an essential aspect of the program to ensure that: optimal coverage is achieved, azithromycin is distributed appropriately and safely, and strategies for further performance improvement are identified. Please consider the following:

- Supervisors should receive training in supportive supervision for MDA.
- The supervisor should present themself as a member of the team.
- The most important role of the supervisor is to support and troubleshoot, solving any problems that may arise.
- The key question a supervisor should ask of the distribution team is "How can I help?"
- Evaluation of an individual's performance is part of supervision but in a supportive supervision framework, evaluation is conducted as a means to improve the performance of the individual and that of the team.
- A supportive supervisor should be a strong communicator, a team builder, and a mentor.
- The supervisor's task is to assess the distribution exercise and the work of community drug distributors (CDDs), and gather information on any cases of SAEs.
- The supervisor's goal is a successful MDA, which is defined as an MDA that has been done safely and efficiently, and has achieved the optimal coverage of 80% or more.

For further information on how to train supervisors in supportive supervision techniques, please refer to the manual "Supportive Supervision for Mass Drug Administration for PCT-NTDs" found on the ICTC website.

Azithromycin Supply Chain Management Guide

The production of azithromycin spans three continents, involving a sophisticated, high-tech supply chain that ensures communities receive the medication they need. At the last mile, community drug distributors (CDDs) collect and transport the medicine using locally appropriate methods. In South Ethiopia's Damot Gale Woreda, Bekere Tonku guides a donkey carrying a supply of azithromycin to Wofare Shanka to assist with MDA in communities. *Photo Credit: Brent Stirton/Getty Images for International Trachoma Initiative*

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Bien Fasil Worku and Bezu Tekeleyes Abebe carefully inspect bottles of azithromycin in a storage warehouse where shipments are prepared for nationwide distribution. Allocations will be sent to health centers across Ethiopia who will then subdivide the drugs to individual distribution teams for local delivery. *Photo Credit: Brent Stirton/Getty Images for International Trachoma Initiative*

1. Shipment Planning and Coordination

1.1: Introduction to Azithromycin for the Supply Chain Manager

- The target audience for this section of the Azithromycin Management Guide (AMG) is primarily any person or organization that is responsible for the supply chain management of azithromycin for trachoma control and elimination, including quantification, shipment planning, customs clearance, transportation, warehousing, inventory management, distribution, and reverse logistics.
- Azithromycin for trachoma is an antibiotic donated by Pfizer Inc. (Pfizer) through the International Trachoma Initiative (ITI) to countries engaged in the elimination of trachoma. The drug is donated specifically for MDA to the national trachoma or NTD program.
- Azithromycin is presented in two forms: powder for oral suspension (POS) and tablets:
  - POS:
    - When reconstituted with water, one bottle of POS contains 1,200mg in 30ml (200mg/5ml).
    - The powder is white and has a pleasant fruit taste.
    - Three dosing cups are provided with each bottle of POS.
    - Lot numbers (also called batch numbers) and expiry dates appear on each bottle. POS has a shelf life of 24 months after manufacture (five days after reconstitution).
    - Azithromycin expires on the last day of the month indicated on the bottle.
  - Tablets:
    - One bottle contains 500 tablets, 250mg each.
    - The tablets are oval in shape and bright pink in color.
    - Zithromax® will have **"Pfizer"** imprinted on one side and **"ZTM 250"** on the other.
    - Azithromycin tablets will have **"L"** stamped on one side and **"590"** stamped on the other.
    - Lot numbers and expiry dates appear on each bottle. Zithromax® tablets have a shelf life of 48 months after manufacture (36 months after opening).
    - Azithromycin tablets have a shelf life of 24 months after manufacture. Additional stability testing is underway to confirm a longer shelf life.
    - Azithromycin expires on the last day of the month indicated on the bottle.

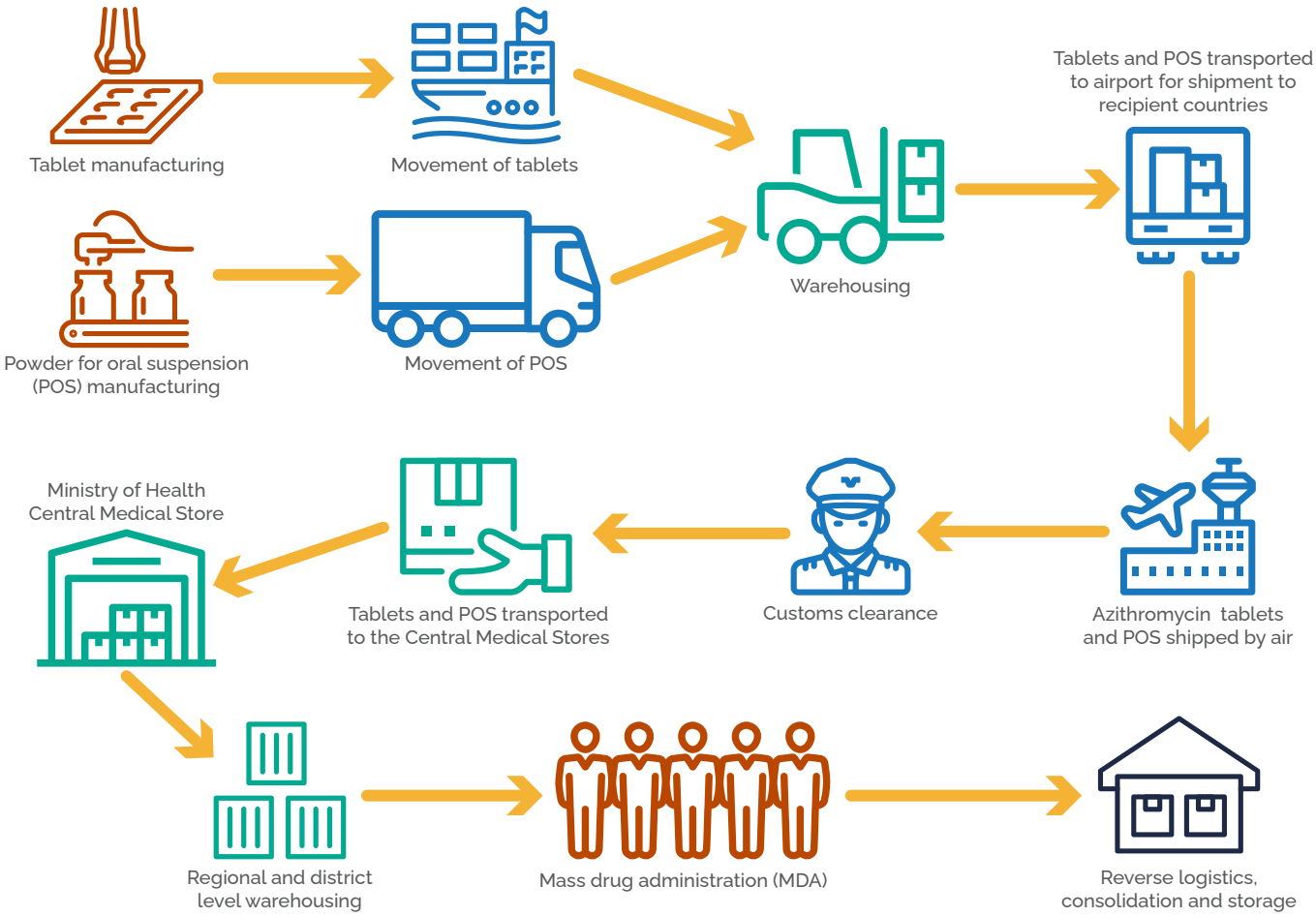
Photo credit: Brent Stirton/Getty Images for International Trachoma Initiative

Pfizer donates azithromycin for the exclusive purpose of trachoma control through MDAs in approved districts, research, and/or surgery. Azithromycin must not be used for any other purpose.

Photo credit: Brent Stirton/Getty Images for International Trachoma Initiative

- For both POS and tablets, the bottle labels are a unique and distinctive purple, with writing in English and in French. The Zithromax® label states "**Zithromax® - Donation for treatment of trachoma only**" while the azithromycin label states "**Azithromycin - Donation for ITI only**." No other packaging is used for donated azithromycin.
- This section will help supply chain managers ensure that azithromycin is managed effectively and according to the terms of the donation as outlined in the memorandum of understanding (MOU) between the Ministry of Health (MOH) and ITI at The Task Force for Global Health. (See Annex 5 for excerpt of obligations of ITI and the MOH as outlined in the MOU.)
- For the National Program Coordinator (NPC) and partners, this section complements the first half of this guide to provide knowledge of azithromycin supply chain management.

Azithromycin Supply Chain Overview



1.2: Preparing for Shipment

The supply chain's goal is to deliver azithromycin to those who need it for trachoma at the right place, at the right time, and in the right quantity. Once the country's application has been approved by TEC, supply chain managers are requested to follow the steps outlined below to ensure that the correct amount of azithromycin is shipped by ITI in a timely manner.

Prior to azithromycin arriving in-country, ITI and the recipient country will complete a number of steps:

1.2.1: In-Country Inventory

- ITI will send an inventory form and instructions to the program prior to organizing a shipment.
- A physical inventory should start immediately after MDA.
- The completed inventory report should include stocking locations, lot numbers, expiry dates, quantities in usable and unusable condition, and losses due to damage, expiry, or wastage.
- The inventory report should be submitted to ITI in the requested format no later than 10 days after MDA. Late reporting may result in delays for subsequent shipments.

1.2.2: Approved Districts and Quantities

- ITI will confirm the districts and quantities approved to receive the azithromycin donation with the NPC.
- ITI will deduct the total amount of usable azithromycin inventory in-country from the approved request to calculate the amount to ship.

1.2.3: Shipment Calculation

ITI calculates the amount of azithromycin tablets and POS that a country receives based on the following assumptions:

- 98% of a population is 6 months of age or older and is therefore eligible for azithromycin tablets or POS (eligible population).
  - 80% of the eligible population is estimated to be 7 years or older and thus will receive azithromycin tablets.
  - 20% of the eligible population is estimated to be between the ages of 6 months and 7 years of age and thus will receive azithromycin POS.
- 2% of the population is estimated to be 0–6 months of age and therefore is not eligible for treatment with azithromycin. These children should be treated with TEO. ITI does not provide TEO to countries.
- ITI will assess the utilization of both POS and tablets to ensure this ratio is appropriate and work with the NPC to adjust as needed.

If a country has official population proportions based on demographic information that differs from above, please advise ITI.

Further reductions may be made by ITI as informed by supply availability and recommendations by TEC. Any changes needed will be communicated to the countries by ITI.

A shipment of 3,159,522 azithromycin treatments — including tablets from Alembic Pharmaceuticals and powder for oral suspension — arrives at Bole International Airport aboard an Ethiopian cargo flight. This marks the first-ever photograph capturing the interior of a cargo plane in Ethiopia. *Photo credit: Brent Stirton/Getty Images for International Trachoma Initiative*

1.2.4: Shipment Calculation Tool

The Shipment Calculation Tool was designed to automate the shipment process and provide shipment quantities to each country when orders are initiated. A sample Shipment Calculation Tool is included in **Annex 6**.

The output of the Shipment Calculation Tool is determined by the following data points provided by the user: Approved treatments for MDA, Approved treatments for surgery or research, reported in-country inventory, and the requested ratio for POS and tablets.

Based on the input, the Shipment Calculation Tool will calculate the actual shipment quantity and provide a detailed summary of the number of bottles, cases, pallets, and treatments for POS and tablets.

To ensure the Shipment Calculation Tool is effective and accurate, the national program must confirm the information entered in the Shipment Calculation Tool.

1.2.5: Contact List

- Prior to each shipment, ITI will request updated contact information for:
  - NPC
  - Importer of record
  - Consignee (organization or person to whom the product is officially sent or delivered)
  - Point of contact at the "deliver to" address (physical address to which the shipment should be delivered)
  - Person responsible for customs clearance
  - Anyone else who should be notified of the upcoming shipment
- The names, addresses, and telephone numbers of these points of contact will be included in all subsequent shipping documents.
- The contact list (see **Annex 7**) needs to be up-to-date to avoid any delays in shipping.

Supply chain staff conduct physical inventory counts of azithromycin at the Manica provincial warehouse in Mozambique following mass drug administrations. *Photo credit: Scott McPherson for RTI International*

1.2.6: Certificate of Donation, Pro Forma Invoice, and Commercial Invoice

Once ITI has received the updated contact list, the order is initiated. Pfizer generates the respective shipping documents, including the certificate of donation, pro forma invoice, and commercial invoice for the shipment.

Generally, a certificate of donation (see Annex 8) will contain the following information:

1. Quantity of azithromycin to be donated to the country program
2. Statement that the azithromycin is a donation that has no commercial value and meets the criteria for duty-free entry and exemption of all fees related to commercial processing
3. Statement that the azithromycin donation is only for use in trachoma program activities

Generally, a pro forma invoice (see Annex 9) will contain the following information:

1. Brief product description
2. Quantity of azithromycin to be donated
3. Consignee name and address
4. "Deliver to" name and address
5. Incoterms
6. Mode of transport
7. Port of entry

The commercial invoice will contain the same information as the pro forma invoice along with:

1. Value of the donation for tax and duty purposes
2. Lot number, manufacturing date, and expiration date
3. Invoice number

1.2.7: "Green Light" for Azithromycin Shipment

A "green light" is a confirmation message from the NPC to ITI stating that the country is ready to receive the azithromycin shipment. The NPC must confirm that the needed preparations have been completed before sending the green light. Azithromycin is not shipped until the NPC can answer "Yes" to each question:

1	**Communications:** Has the customs brokerage company been informed of the delivery details including the expected quantities?
2	**Duty Exemption:** Are all the documents required for customs duty exemption and importation authorization prepared and ready?
3	**Import Permit:** Are all the documents required for azithromycin importation authorization prepared and ready?
4	**Customs Clearance Fees:** Are the necessary funds available to pay the customs clearance fees upon delivery arrival? These fees are invoiced by the customs brokerage company and must be paid promptly to enable the release of the shipment.
5	**Transport of Parcels:** Are the necessary resources available to ensure the transport of parcels from the port of entry/airport to the central medical stores (including financial resources, transportation means, and coverage for any potential loading and unloading fees)?
6	**Warehouse:** Does the central pharmacy or Central Medical Stores (CMS) have adequate space and temperature controlled facilities to properly store the medicines?
7	**Storage Fees:** Are the funds available to pay the storage fees at the agreed storage location if there are fees to be paid?
8	**Distribution:** Is the country ready for the distribution of azithromycin? Is there a distribution plan in place?
9	**MDA Date:** What is the confirmed MDA date?

Once the "green light" is given, changes to the shipping documents or the physical shipment will not be possible.

Once the answer to all questions is "Yes", the NPC will send the green light notification to ITI that the azithromycin can be shipped. If the answer to any of the above questions is "No", ITI will work with the NPC to address any outstanding issues.

1.2.8: Final Shipping Documents from ITI

Once the green light has been received, ITI will send the final shipping documents to the NPC. These documents include:

- ❑ Certificate of Donation
- ❑ Pro Forma Invoice
- ❑ Commercial Invoice
- ❑ Packing List
- ❑ Certification of Analysis
- ❑ Certification of Origin
- ❑ Air Waybill or Bill of Lading (see Annex 10)

If any additional documentation is required by the country for customs clearance, ITI should be notified immediately at the beginning of the shipment process. Original documents can be sent via courier if they are required for customs clearance.

1.2.9: Final Arrangements for the In-Bound Shipment

Once all the final documents have been received, the NPC should notify the clearing agent of the expected date of arrival.

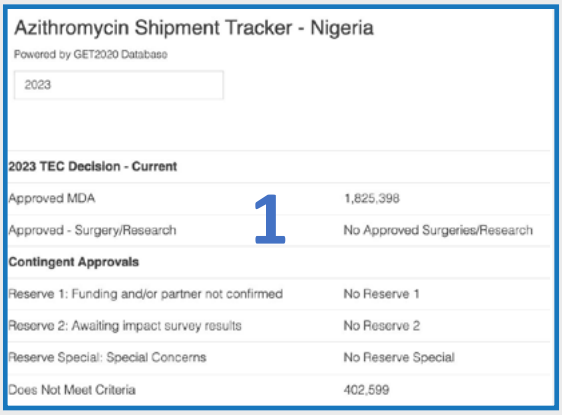
1.2.10: The Azithromycin Shipment Tracker

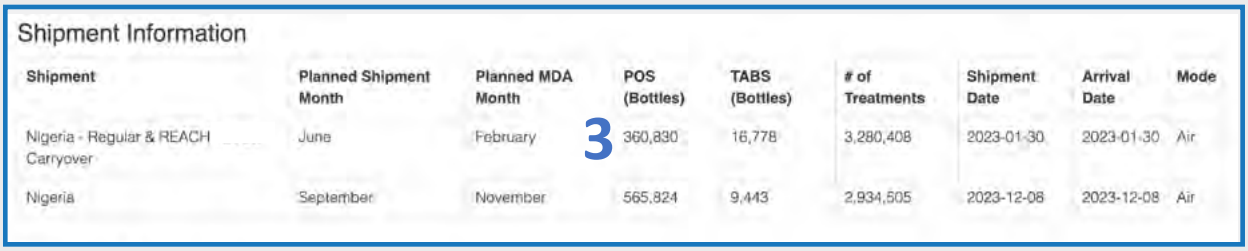
The Azithromycin Shipment Tracker is a web-based tool that provides users with real-time access to information about recent and upcoming shipments of azithromycin to recipient countries in an easy-to-follow electronic format. The Tracker provides information about the quantities of drugs requested via the azithromycin application, current decisions made by TEC, quantities shipped year-to-date, quantities remaining to be shipped, expected arrival date, and mode of transport. To subscribe and begin receiving automated email updates on shipments via the Tracker, visit the following link: supplychain.trachomadata.org/subscriptions.

Azithromycin Shipment Tracker

Azithromycin Shipment Tracker by Country

1. Current Trachoma Expert Committee (TEC) Decision
2. Current Year's Shipment Summary
3. Shipment Information
4. Shipment Progress
5. MOU Status





Once drugs arrive at the port of entry in the recipient country, the next steps are offloading and customs clearance. Customs clearance agents will inspect the shipment, ensure that it is in compliance with the recipient country's import rules and regulations, and verify that all applicable taxes and fees have been paid before the drug is released for transport to the central or provincial medical stores. This image shows one of seven separate shipments to Ethiopia in 2017 arriving at Addis Ababa Bole International Airport. *Photo credit: Tesfamichael Afework for the Pharmaceuticals Fund & Supply Agency, Ethiopia*

1.2.11: Customs Clearance

ITI ships donated azithromycin to a designated port of entry. The country is responsible for clearing the product and transporting it to Central Medical Stores. Once azithromycin has arrived in the country, the NPC should work closely with their customs clearing agent for timely clearance of the shipment. The time required to complete customs clearance may vary from a few days to several weeks. However, all the necessary steps should be taken to ensure the timely clearance of the drug to avoid:

- Demurrage charges for late clearance. The national program, per the MOU, is responsible for all costs incurred to import the donated drug. A description of the MOU is found in Annex 5.
- Physical damage
- Loss of the drug (e.g., theft, expiry)

1.2.12: Confirmation of Receipt

When the shipment has been cleared from customs, CMS should provide confirmation of the total physical quantity of bottles of azithromycin (both tablets and POS) received in good condition. A confirmation of receipt form (see **Annex 11**) should be sent to ITI within seven days of arrival of the shipment in-country. The confirmation should be sent after a physical inventory count and inspection of the products received (see **Section 2.2.1 – Physical Inventory of Azithromycin**). Any damage or loss that occurred in the shipment process or quantities taken for quality assurance testing should also be noted, with the exact amount of bottles lost or damaged, on the confirmation of receipt form.

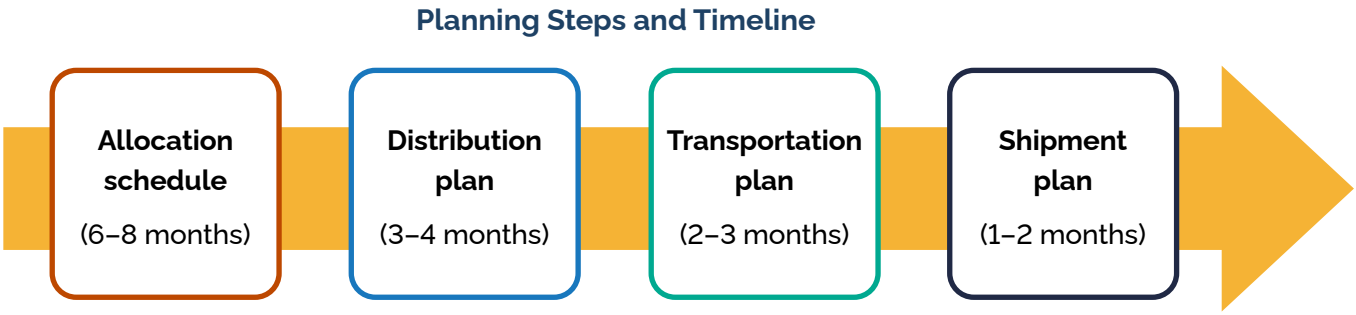
Bezu Tekeleyes Abebe, a supply chain worker, carefully inspects a bottle of azithromycin upon its arrival at the storage facility in Addis Ababa, Ethiopia. As part of the quality assurance process, supply chain workers verify the total quantity and condition of both bottles and POS before distribution for MDA. *Photo Credit: Brent Stirton/Getty Images for International Trachoma Initiative*

2. In-Country Supply Chain Management of Azithromycin

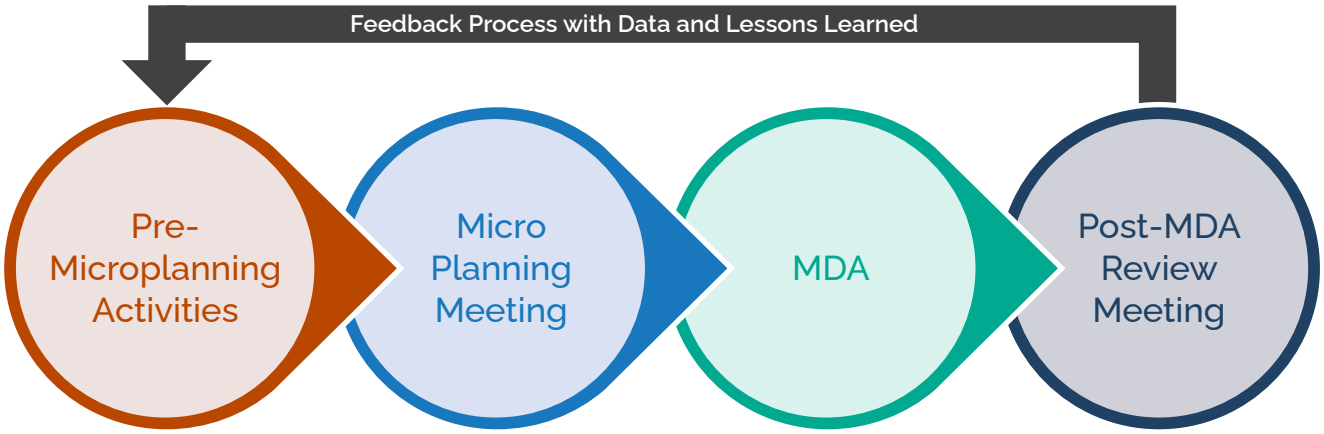
2.1: Drug Movement in Preparation for MDA Schedule

Planning for drug movement through the in-country supply chain from Central Medical Stores to distribution sites is a critical part of preparing for MDA and should be done early in the micro-planning process. Detailed planning for drug movement involves the creation of an allocation schedule, distribution plan, transportation plan, and in-country shipment plan. These plans should be agreed upon by key implementing partners.

The following diagram shows the major steps:



Micro-Planning Process "Quick Reference" Guide



- Establish timing of MDA
- Create and update community registers
- Organize participants
- Use evidence and lessons learned from previous MDAs
- Organize budget for micro-planning activity

- Set up MDA time table
- Plan for training
- Plan for the organization of distribution/ distribution strategy
- Problem solving
- Set coverage target
- Plan for supervision
- Plan for reporting
- Plan for MDA logistics

- Implement and execute the micro-planning outcome

- Provide feedback with teams
- Discuss lessons learned
- Make recommendations for the following year's MDA
- Discuss and plan impact surveys, if indicated
- Discuss and plan coverage surveys, if indicated
- Indicate parts of the micro-plan that need improvement

MDA Logistics Planning in Two Steps

1. Draw the MDA distribution network:

2. For each distribution point, define and budget:

- How many people will be treated at each distribution node
- How much azithromycin will be needed for each distribution node
- When to deliver
- Where to deliver
- How to transport it (transportation mode)
- Cost of delivery
- Design and budget for a reverse logistics plan

The number of tablets per treatment and quantity of POS per treatment may vary by country.

The ratio of tablets to POS may vary by country.

2.1.1: Allocation Schedule

An Allocation Schedule (see Annex 12 for template) gives an estimate of the quantity of azithromycin required to treat the target population of the country by district.

- As a first step, the supply chain manager must create an allocation schedule to determine the quantity of azithromycin that should be sent to regional/district storage facilities based on TEC-approved district allocations.
- Azithromycin must only be allocated to districts that have been approved by TEC. Allocating drug to non-approved districts is considered a violation of the MOU and will jeopardize a country's potential to receive azithromycin in the future.
- Based on the target population in each of the districts, the number of bottles of tablets and POS required are calculated using the following formula.
  - 98% of a population is 6 months of age or older and thus eligible for azithromycin MDA.
    - It is generally estimated that 80% of the eligible population is 7 years of age or older and will be treated with tablets.
    - Similarly, 20% of the eligible population is estimated to be 6 months to 7 years of age and will be treated with POS.
    - ITI uses a default allocation of 80% tablets and 20% POS at the district level. However, this ratio may vary by country. If a country wants to use a different ratio based on population or distribution data, they should notify ITI.
    - The gross number of bottles calculated for each district should take into account the allocation percentage approved by TEC. For example, TEC recommended that, due to the 2023 azithromycin shortage, global shipments be reduced from 95% to 80% allocation until supply increased.

$$\text{Gross tablets required (bottles)} = \frac{\text{Total approved} \times 0.8 \times \text{number of tablets/treatment}}{500}$$

$$\text{Gross POS required (bottles)} = \frac{\text{Total approved} \times 0.2 \times \text{quantity of POS/treatment}}{30}$$

$$\text{Tablets required (cartons)} = \frac{\text{Gross tablets required (bottles)} - \text{on hand inventory (bottles)}}{24}$$

$$\text{POS required (cartons)} = \frac{\text{Gross POS required (bottles)} - \text{on hand inventory (bottles)}}{48}$$

The required number of cartons should always be rounded up to integer values.

2.1.2: Distribution Plan

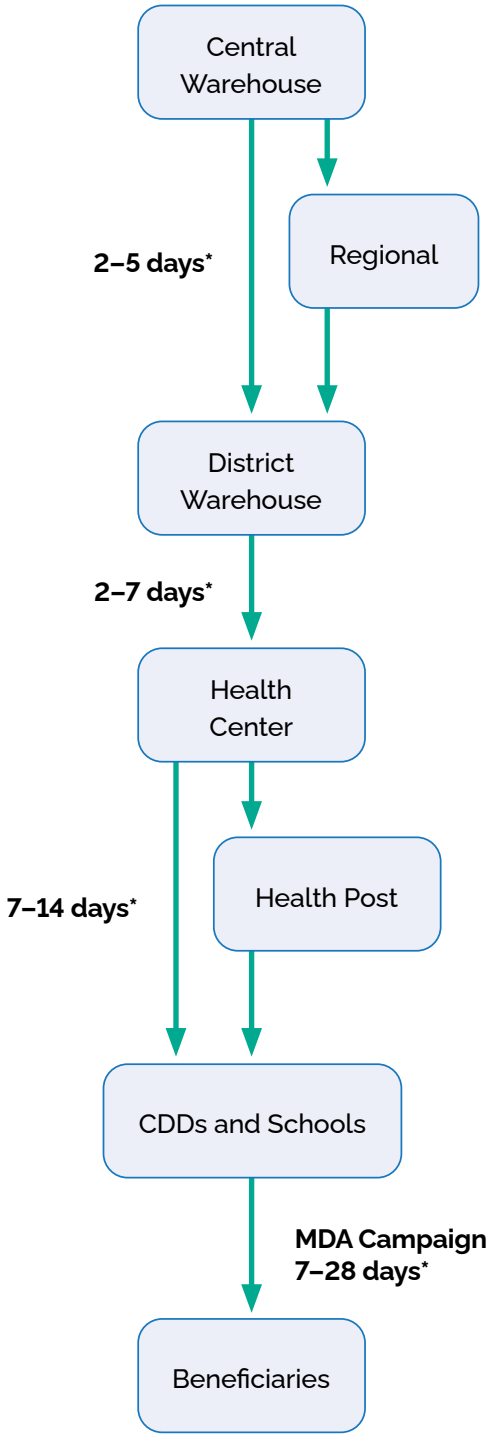
Once the allocation schedule has been created, the supply chain manager must develop a distribution plan. The distribution plan outlines the physical flow of azithromycin from CMS to the various distribution sites, including all intermediate stops along the way. The distribution plan should also show the length of time required to move drug from one site to the next.

- The distribution plan should include the quantity of drug to be moved, the physical flow of the drug, and the earliest and latest delivery dates to each district.
- All facilities receiving azithromycin must ensure sufficient storage capacity for the product by the earliest delivery date.
- It is advisable that all districts receive the azithromycin supply in the full quantity required for the MDA at least two weeks before the distribution begins.

Azithromycin can only be distributed in specific districts approved by TEC.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

Example of physical product flow:



**for illustrative purpose only*

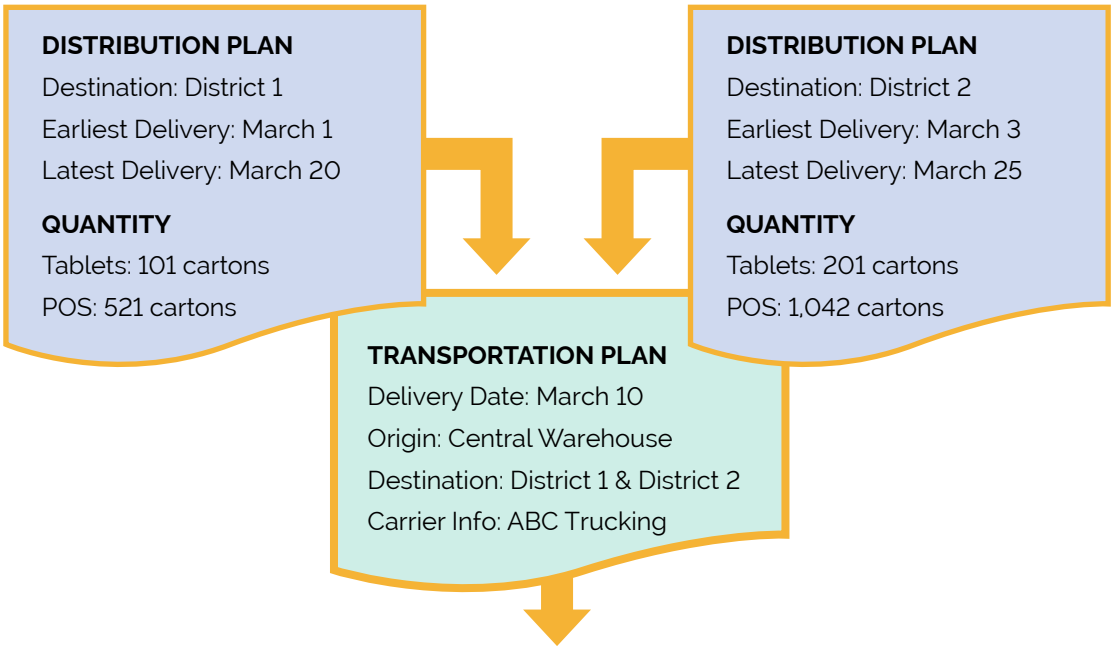
2.1.3: Transportation Plan

After the distribution plan is created, transportation modes, routes, and dates should be fixed for all the shipments in order to create the transportation plan.

- If the NPC or supply chain manager does not have direct control over the shipment dates and transportation mode, coordination will be necessary with the appropriate local, regional, or national authorities to ensure timely shipment of azithromycin before the distribution begins.
- If a district requires less than a full truckload of azithromycin, its delivery should be combined with that of neighboring districts, such that they can all be served by one truck. Opportunities should also be sought to combine azithromycin shipments with any other medical supply shipments including other NTD drugs going to the same destination from the central warehouse.
- Drugs intended for different districts need to be properly labeled and, if possible, separated from each other to avoid mixing of allocated quantities and lot numbers.
- If a third party transportation provider is used, a contract must be signed by the MOH to protect against damage or loss of the product during transportation.

2.1.4: In-Country Shipment Plan

- Finally, after planned delivery dates are confirmed by the transportation provider, a detailed shipment plan should be created, to include exact dates, shipment quantity, origin, destination, and carrier information.
- The shipment date and time should be confirmed with the receiving facilities after the plan is made. Always communicate with the receiving facility before sending the shipment to avoid any issues with the shipment date.



SHIPMENT PLAN
(from Central Warehouse)

Serial no.	Date	Destination	Quantity (Tablets) in cartons	Quantity (POS) in cartons	Carrier Name/ Phone number
1	March 10	District 1	101	521	ABC Trucking Phone number: xxxx
2	March 10	District 2	201	1,042	

Photo credit: Brent Stirton/Getty Images for International Trachoma Initiative

2.1.5: Azithromycin Product Specifications

Suppose Country X uses an average of 3 treatments/bottle of POS and 131 treatments/bottle of tablets, azithromycin product and packaging specifications would be as follows:

Azithromycin for Trachoma	**Powder for oral suspension**	**Tablets** (Bottles of 500)
Average Treatments/Bottle	3	131
Bottles per Carton	48	24
Dosing Cups per Carton	144	N/A
Cartons per Pallet	32	54
Average Treatments/Pallet	4,608	169,776
Carton Dimensions (cm.)	36.5 x 28 x 22	36 x 24.4 x 16
Pallet Dimensions (cm.)	80 x 120 x 92	80 x 120 x 100
Carton Weight (kg.)	3.5	6.7
Pallet Weight (kg.)	132.0	379.0
Shelf Life (Unopened)	24 month	48 months
Shelf Life (Opened)	5 days after reconstitution	36 months

Azithromycin expires on the last day of the month indicated on the bottle.

Azithromycin cannot be distributed after its expiration date!

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

2.2: Managing the Azithromycin Inventory

Receiving and storing azithromycin

- Ensure that there is sufficient storage space.
- Prepare and clean the areas used for receiving and storing the cartons.
- Count and inspect received cartons in person (do not rely on paperwork).
- Inspect the cartons for any damaged or expired product.
- If the drugs are damaged or expired, follow the procedure described in the section 2.2.5: Managing Damaged or Expired Drugs.
- Update the stock card immediately after receiving the cartons (see details in the section 2.2.3 – Recordkeeping).
- Complete a transfer form (see Annex 15 for example) each time azithromycin is moved from one location to another. A completed and signed transfer form must be sent back to the origin location (central, provincial, district) and a copy maintained at the receiving location. With each movement of the drug, ensure the lot numbers and quantities match those recorded on the transfer form.

Guidelines for storage

Arrange the products in the store according to the following guidelines:

- Always store the drugs in a secured location with access control. Limit access to authorized staff. Also, limit the number of keys to the storage facility and keep a list of the people who have been given keys.
- As a general rule, all usable drugs should be stored:
  - At least 10 centimeters off the floor
  - At least 30 centimeters away from the walls or other stacks of pharmaceuticals
  - In stacks no more than 2.5 meters high
- Store azithromycin tablets and POS in separate stacks.
- Do not combine bottles of azithromycin that have different lot numbers in the same carton.
- Do not combine tablets from open bottles of azithromycin to make a full bottle — you may inadvertently mix tablets with differing lot numbers and expiry dates.
- After each issue or receipt of the drug, all stacks should be re-arranged to maintain the First Expiry, First Out (FEFO) order.
- Arrange the cartons so that the identification labels and expiry dates are visible.
- Store azithromycin in a facility where the temperature is below 30˚ Celsius.
- Azithromycin should not be exposed to direct sunlight.
- Segregate damaged or expired drugs from usable azithromycin. Clearly mark the damaged or expired drugs as follows: **"DO NOT USE — Damaged/Expired products"** (See section 2.2.5: Managing Damaged or Expired Drugs).

Store azithromycin in a manner to facilitate FEFO. Azithromycin with the earliest expiry date should be used first.

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

Improving Security of the Azithromycin

Most countries will have certain task forces focused on various drug-related issues such as counterfeit drug control, drug abuse, and other pharmaceutical concerns. National trachoma programs can identify and liaise with such task forces and other critical partners (traditional leaders, medical store authorities, patent medicine vendors union, pharmaceutical societies, etc.) to implement measures to prevent the theft of azithromycin, or to track diverted azithromycin in the event of theft.

2.2.1: Physical Inventory of Azithromycin

The purpose of a physical inventory is to reconcile the on-hand inventory as recorded on the stock card and the physical inventory at the storage facility. When conducting a physical inventory, ensure that:

- All products in storage are counted.
- No receipts or issues take place during the counting process.
- The process is completed as quickly as possible in order to resume normal operations.

Once a year, following MDA, ITI will request a physical inventory of azithromycin. A sample inventory form is included as Annex 13.

Plan:

- ❑ Plan a specific date and time for the physical inventory.
- ❑ Identify the persons who will carry out the inventory.
- ❑ At least two people should conduct the inventory.
- ❑ To avoid a conflict of interest, the person in charge of the inventory should not participate in the counting process, but should be available at the site to show the inventories.

- Phoning the districts for a mid-year inventory update is sufficient, but should not be used in lieu of the annual physical inventory.
- A physical inventory should be conducted at the end of each MDA campaign.

Organize the storage facility:

- ❑ Arrange the azithromycin tablets and POS separately.
- ❑ Arrange the azithromycin tablets and POS by expiry date.
- ❑ Arrange Zithromax® tablets and azithromycin tablets separately and maintain a different stock keeping unit (SKU) for each. Each drug requires a separate stock card for each stack of drugs in the warehouse.
- ❑ All the partially used bottles should be kept separate from the unopened bottles.
- ❑ Separate any damaged or expired drug from usable inventory.
- ❑ For ease in counting, group bottles according to their lot number and expiry date.

Count the products:

- ❑ A team of two people should be assigned to a storage facility.
- ❑ Count one location at a time and record separately by expiry date group. One person should count, and the other person should keep the record (use the **Physical Inventory Form** included as Annex 13).
- ❑ Count the number of bottles per expiry date group.
- ❑ Any reconstituted POS bottles should not be included in the inventory but disposed of within five days of reconstitution. The disposal of reconstituted POS should be done following the MDA and should not be returned to the storage facility.
- ❑ Record the number of opened bottles and unopened bottles on the Physical Inventory Form provided by ITI.
- ❑ For tablets, be sure to count the number of bottles and not the number of individual tablets.

Photo credit: Brent Stirton for the International Trachoma Initiative

Update the stock card:

- ❑ Once counting is finished, reconcile the total number of bottles counted with the inventory quantities recorded on the stock card.
- ❑ If there is any difference, add or subtract the number of bottles on the stock card under the Loss/Adjustment column.
- ❑ Clearly record the date, quantity difference, and write **"Physical Inventory."**

Take actions:

- ❑ If the result of the physical inventory differs from the "on-hand stock" of the stock card, report the discrepancy to the NPC.
- ❑ The NPC should report the results of the physical inventory to ITI.

2.2.2: Issuing Azithromycin from Storage

When issuing drugs from storage:

- Follow the FEFO policy at all levels (i.e., central, district, community levels).
- Issue azithromycin in full cartons when possible.
- For district level storage: Always issue in full cartons, if possible. Do not break the carton to issue single bottles unless it is being issued to community distributors.
- Only one carton should be opened at a time to issue bottles at the community level.
- Update the stock card immediately after issuing drugs from storage (see details in the 2.2.3 Recordkeeping section).

Standard Operating Procedures (SOPs) for First Expiry, First Out (FEFO)

Task	Distribute azithromycin according to the FEFO distribution principle
Completed by	Store Pharmacist–in-charge, Pharmacy Technician or Medical Store Managers
Purpose	To ensure that azithromycin is distributed before it expires
When to Perform	Whenever azithromycin is being issued for MDA or being transferred to another storage location

Step	Action
1	Mark expiry dates on the outside of every carton or box making sure that the dates are visible at a distance.
2	Place cartons or boxes of azithromycin so that stocks first to expire are stacked in front or on top of stocks that will expire later.
3	Issue azithromycin stocks from the front to back or from the top to bottom so that azithromycin stock that will expire sooner will be issued first.

Do not follow First-in, First-out (FIFO)

Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

2.2.3: Recordkeeping

Recordkeeping is the most essential part of inventory management. Azithromycin inventory is accounted for on two important forms (see **Annex 14** and **Annex 15** for examples):

- Stock cards
- Transfer forms

Use these two forms to keep track of azithromycin. All storage facilities should use these two forms to record current stock and the history of all transactions or adjustments (i.e., product receiving, issuing, distribution, and physical inventory reconciliation). Transfer forms must be used each time azithromycin is transported from one location to another.

As a donated product only to be used for the elimination of trachoma, azithromycin must be assigned its own SKU and must be stored separately from generic azithromycin to prevent the azithromycin from being used by the general health system.

Stock Card (see Annex 14 for example):

- Stock cards are used to record receipts, issues, and adjustments for azithromycin stored in a particular location.
- Zithromax® tablets and azithromycin tablets should have separate SKUs and require separate stock cards. Attach a separate stock card to each stack of drugs in the warehouse.
- Azithromycin tablets and POS require separate stock cards. Attach a separate stock card to each stack of drugs in the warehouse.
- As a best practice, create a new stock card for open bottles to facilitate counting during physical inventory.

Each time azithromycin is received or issued, it should be entered onto the stock card and inventory should be updated.

- Physical inventory reconciliation should be done on an annual basis (see section 2.2.1 on physical inventory) and stock cards should be updated accordingly.
- Records of all the stock cards should be kept for at least two years at each location.

Transfer Form (see Annex 15 for example):

- This form should be used to issue azithromycin from one storage facility to another or to community distribution teams.
- Two copies of the form should be used for recording each transaction; one copy will go to the destination along with the carrier (i.e., person responsible for transportation) and the other copy will be kept in the origin location for recordkeeping purposes.
- Both copies of the form should have the same serial number.
- The first part of the form records the origin, destination and the name of the person transporting the shipment along with the quantity issued. This part should be filled in at the origin and signed by both the carrier and issuer for agreement.
- The second part of the form should be filled in at the destination.
- Any damaged quantity in the shipment should be recorded on the form and it should be signed by both the receiver and the transporter.
- The drug distribution teams should use the same form when receiving the bottles of azithromycin.
- Unused quantities should be returned to the designated stocking location and the stock card updated. See the section below on managing used and empty bottles. Any wastage of drugs should also be recorded.
- ITI requires that records of all the transfer forms be kept for at least two years.

2.2.4: Managing Close-Dated Drugs

Like all other medicines, azithromycin has a specific expiry date.

- Azithromycin tablets and POS have a shelf life of 24 months from the date of manufacture. (As of the printing of this guide, additional stability testing is being conducted to confirm a longer shelf life for azithromycin tablets).
- Zithromax® POS has a shelf life of 24 months from the date of manufacture (five days after reconstitution).
- Zithromax® tablets have a shelf life of 48 months from the date of manufacture (36 months after the bottle has been opened).

Because of the high value of the product and high logistics cost involved, it is important to plan ahead to avoid any wastage of the donated drugs due to expiration.

Azithromycin expires on the last day of the month indicated on the bottle.

Azithromycin cannot be distributed after its expiration date!

Actions to take depending on expiry date of azithromycin

POS	Tablets	Actions to be taken prior to distribution	Actions to be taken during and after distribution
Less than 6 months **Category A** ***Urgent action required***	Less than 12 months **Category A** ***Urgent action required***	▶ Separate the lot that is due to expire from other inventories. ▶ Use all the products from this lot first in the distribution.	▶ Look for opportunities to use the drugs in other districts/areas where the distribution has not yet started or finished. ▶ If no such use is possible, report the quantity immediately to the NPC. ▶ If a large quantity of such inventory is present in the country (more than 1,000 bottles of tablets), report it to ITI immediately.
6 months to 18 months **Category B** *Inventory Alert*	12 months to 36 months **Category B** *Inventory Alert*	▶ Separate these drugs from other inventories. ▶ Use the products of this category after using category A products.	▶ Make sure to report such inventory of drugs clearly in the post-MDA inventory report.
18 months and more **Category C** Normal inventory	36 months and more **Category C** Normal inventory	▶ No action necessary. Just follow FEFO policy.	▶ Complete the post-MDA checklist in a timely fashion.

2.2.5: Managing Damaged or Expired Drugs

Damaged or expired drugs should NOT be administered under any circumstances. Certain types of damage may qualify as a "product quality complaint" and should be reported in accordance with the safety reporting requirements that are outlined in the MOU (see page 85 for more information). This includes:

1. Tablets or POS that have expired
2. Punctured or leaking bottles
3. Broken, crushed, or wet tablets
4. Hard or cakey POS that will not mix
5. Bottles of reconstituted POS remaining after the completion of the MDA campaign that will not be used within five days
6. Bottles without an expiry date or with a label that is illegible

Note: If the carton or bottle is damaged (e.g., wet or crushed) and the product inside is still in good condition, then the drug can be administered.

If azithromycin is found in any of the six conditions listed above or any other related conditions suggesting damage or expiration, immediately notify the NPC and ensure the total loss is reflected on the inventory report shared with ITI.

2.2.6: Azithromycin Disposal Methods

The disposal of the unusable drugs should be done following the six steps below:

Step 1	Separate the damaged or expired drug from the usable inventory.
Step 2	Attach proper cautionary sign or label indicating that the drug is damaged or expired.
Step 3	Inform NPC immediately.
Step 4	Select the appropriate disposal protocol listed in the table below.
Step 5	Plan for the disposal (selection of method, site, date, and required resources).
Step 6	Dispose of damaged or expired products according to guideline.

One of the following disposal methods should be used to dispose the damaged or expired drugs:

Priority	Disposal method	Methods
First	**Country medicine disposal guideline/protocol**	Use the MOH and/or environmental regulations of the country for the disposal of antibiotic tablets and POS.
Second	**Manufacturer recommended disposal method**	Wet down to render unusable, then incinerate.
Third	**WHO guideline**	For solid antibiotics (tablets), suitable methods are waste encapsulation and sending to landfills. Medium or high temperature incineration (cement kiln incinerator). For antibiotic POS, it can be diluted with water, left to stand for several weeks and then discharged to sewer.

Post-MDA Checklist:

- ❑ Perform reverse logistics (i.e., the physical flow of azithromycin from the distribution points back to a centralized storage location at the regional or district level)
  1. Collect empty azithromycin bottles designated for disposal. If the bottles will be repurposed, ensure labels are made unreadable to prevent confusion about their contents. This can be done by covering the label with a permanent black marker.
  2. Return all usable azithromycin to the regional and district level store as soon as possible after MDA (preferably within two weeks).
  3. Complete the post-MDA physical inventory.
  4. Dispose of expired, damaged, or unusable azithromycin (see Section 2.2.5 –Managing Damaged or Expired Drugs).
- ❑ Collect all data forms that have been prepared and ensure that they are correctly filled out.
- ❑ Perform data quality assessment:
  1. Analyze inventory results and accuracy.
  2. Analyze coverage rate based on districts' distribution numbers.
  3. Analyze coverage rate based on districts' reported leftover inventory.
  4. Analyze coverage rate based on leftover physical inventory counting.
- ❑ Combine all data forms and report total number of treatments distributed to the country program manager.
- ❑ Debrief with MOH team and share key findings.
- ❑ The NPC is required to report final distribution figures to ITI within 90 days of completion of the campaign. The distribution report is submitted annually according to MOU. (See Annex 16 for District Level Distribution Summary Report form.)

2.2.7: Managing Empty Bottles

All empty bottles must be defaced using a black, permanent, and waterproof marker by placing an **"X"** mark on the front of the label.

Use one of the following methods to dispose of empty bottles:

Priority	Disposal method	Methods
First	**Country medicine disposal guideline/protocol**	▶ Use the MOH and/or environmental regulations of the country for the disposal of empty pharmaceutical containers.
Second	**Reuse**	▶ The bottles can be reused after they are defaced using a permanent marker. The azithromycin label is pressure sensitive and cannot be peeled off easily.
Third	**Recycle**	▶ If the bottles are not reused, then they can be sent to a plastic recycling facility (if available). The permanent labels make the bottles unacceptable by some recycling facilities.

Photo credit: Brent Stirton/Getty Images for International Trachoma Initiative

Habitamawa Homja, a health worker at the Boditi Health Center in Wolaita, South Ethiopia, carefully records the newly received azithromycin treatments. As part of the in-country supply chain process, she ensures accurate documentation before distributing the medication for MDA. *Photo Credit: Brent Stirton/ Getty Images for International Trachoma Initiative*

3. Supply Chain Assessments

3.1: Supply Chain Assessments

Supply chain risk assessments are often conducted for countries preparing to receive the azithromycin donation for the first time as well as countries requesting or in need of an assessment. The overall purpose of the supply chain assessment is to collect key information on the supply chain to identify gaps and opportunities.

The initial supply chain assessment is used to assess a country's ability to successfully clear customs, store, manage, and distribute azithromycin. A test shipment of a few pallets of drug will be shipped to the recipient country, and ITI will observe how the shipment flows through the supply chain, from customs to the regional level or district level. If issues are identified, then they must be addressed with corrective action prior to the country's receipt of a larger donation. In addition to the initial supply chain assessment, subsequent assessments may be conducted on a periodic basis to review the current status of the supply chain.

If selected for a periodic supply chain assessment, ITI will be in contact with the NPC. The NPC will be asked to assist in preparation and actively participate in the in-country assessment.

Ultimately, any gaps or opportunities identified should be addressed quickly to further strengthen the functionality of the supply chain. The following key areas are typically observed during a supply chain assessment:

- Customs clearance
- Staffing and organizational support
- Logistics management information system (LMIS)
- Forecasting
- Inventory control procedures
- Warehousing and storage
- Quality assurance
- Transport and distribution
- Product use
- Financing

National programs are encouraged to use the **Azithromycin Supply Chain Assessment Tool** available on trachoma.org to perform self-assessments on an annual basis.

3.2: MDA Transition Planning and Closeout Assessment

As countries approach the final rounds of MDA for trachoma, it is essential they adequately prepare for a smooth transition to the post-MDA phase. To assist with the transition away from MDA, ITI will work with programs to determine the appropriate time to initiate a supply chain closeout assessment, with the two primary objectives of minimizing the amount of azithromycin remaining in country after the last final round of MDA and ensuring the remaining stock of azithromycin is appropriately managed in accordance with the MOU and Azithromycin Management Guide.

One to two rounds prior to the final MDA, ITI will:

- ❑ Send a formal letter acknowledging the country's achievement and explain the importance of conducting a supply chain closeout assessment.
- ❑ Organize a planning meeting with the MOH and implementing partners to discuss the supply chain closeout assessment process and provide situational analysis based on the transition plan.
- ❑ Conduct an in-country visit or desk review and engage in detailed discussions regarding the closeout assessment and facilitate a workshop to guide the implementation of the assessment.
- ❑ Develop a plan for the utilization of the remaining azithromycin inventory, taking into consideration the most recent physical inventory count, expiration dates, and storage conditions.
- ❑ Generate a technical report based on the findings of the supply chain closeout assessment highlighting the strengths and opportunities as well as addressing any outstanding weaknesses and threats.

Countries are strongly encouraged to begin proactively planning for the closeout assessment no later than two to three rounds prior to the expected final MDA.

Even after the final round of MDA, countries with leftover azithromycin are still expected to adhere to the requirements in the MOU between the MOH and ITI. Notably, once MDA is no longer required, the following principles still apply:

- ▶ Ensure that donated azithromycin is used only for the control of trachoma and is not transferred or sold in exchange for money, property or services.
- ▶ Ensure that azithromycin is not used for research purposes without the prior, full, written approval of ITI on behalf of the Trachoma Expert Committee.
- ▶ Ensure that product safety monitoring and reporting processes are in place. If the MOH becomes aware of potential adverse events, at-risk scenarios, and product quality complaints that may be associated with donated azithromycin, they will inform Pfizer through the designated Pfizer regional offices listed in the contact list on Table 1 in Annex A of the MOU.
- ▶ The collection, storage, handling, transportation, movement, disposal, and destruction of all expired azithromycin shall be the responsibility of the MOH in compliance with Pfizer destruction procedures and applicable laws.
- ▶ Annual inventory reports will be requested by ITI to be able to track the use of the drug and to monitor the number of doses remaining until the inventory in-country is zero.

Woyaso Shanka, a health worker, carries a box of azithromycin bottles out of the local health post in Mokosina, South Ethiopia. The medication will be distributed to community drug distributors, who will ensure that community members receive the correct dosages as part of the mass drug administration (MDA) campaign to eliminate trachoma. *Photo Credit: Brent Stirton/Getty Images for International Trachoma Initiative*

In Damot Gale, Wolaita, Ethiopia, community drug distributors Eminet and Mathias administer a dose of azithromycin to an elderly woman as part of a MDA. Mathias carefully measures her height with a dosing pole to ensure she receives the correct dosage, while Eminet hands her the medication to help protect against trachoma. *Photo Credit: Brent Stirton/Getty Images for International Trachoma Initiative*

4. Conclusion

This program manager's guide aspires to inform the planning, implementation, and evaluation of the antibiotic component of the SAFE strategy. Pfizer's donation of azithromycin, and its commitment to making the drug available as long as progress continues, is a major step forward in the global effort to eliminate blinding trachoma. While antibiotics are necessary, they alone are not sufficient to achieve elimination. Success depends on effective use of treatment in concert with efforts towards sustainable prevention — particularly improving access to and utilization of water and sanitation. Success also depends on all of us working together as partners to build even stronger and more effective collaborations. Then, and only then, will we all be able to achieve our collective dream of eliminating blindness, disability, and suffering due to trachoma.

Annexes

Facial cleanliness is an integral component of the SAFE strategy for trachoma elimination. Face-washing removes contagious secretions from the faces of those with trachoma and clean faces are less attractive to eye-seeking flies that transmit the disease. Fantanesh Gedefe washes her face from water stored in the "leaky tin" in the Yilemana Denesa Woreda, Amhara Region, Ethiopia. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

Table of Contents

Resource Materials from the International Coalition for Trachoma Control (ICTC)

Available from: www.trachomacoalition.org

MDA

- Micro-planning for Effective Zithromax® Mass Drug Administration
- Supportive Supervision for Mass Drug Administration for PCT-NTDs
- Zithromax® Mass Drug Administration Trainers Guide
- Transition Planning for Mass Drug Administration of Zithromax®

Facial Cleanliness and Environmental Improvement

- All You Need for F&E: A Practical Guide to Partnering and Planning
- WASH and the Neglected Tropical Diseases – A Manual for Wash Implementers – Ethiopia

Management of Trachomatous Trichiasis

- Epilation Counseling and Training Guide
- Supportive Supervision for Trachomatous Trichiasis Programme
- Training Trichiasis Surgeons for Trachoma Elimination Programs (To be used alongside the WHO yellow manual Trichiasis Surgery for Trachoma)
- Trichiasis counseling guide
- Training curriculum for trichiasis case identifiers
- Organizing Trichiasis Surgical Outreach
- Transition Planning for Trichiasis Management Services
- Women and Trachoma, 2nd edition

Resource Materials from the World Health Organization (WHO)

Available from: www.who.int

- World Health Assembly Resolution 51.11 – Global Elimination of Blinding Trachoma.
- Informal consultation on end-game challenges for trachoma elimination, Task Force for Global Health, Decatur, United States of America, 2021
- Report of the Fourth Global Scientific Meeting on Trachoma, Geneva, Switzerland, 2018.
- Validation of elimination of trachoma as a public health problem Global Scientific Meeting on Trachomatous Trichiasis – Moshi, Tanzania 2012
- Second Scientific Meeting on Trachomatous Trichiasis – Cape Town, South Africa, 2015
- Third Scientific Meeting on Trachomatous Trichiasis – Cape Town, South Africa, 2022
- Water Sanitation & Hygiene 2015–2020: A global strategy for accelerating and sustaining progress on Neglected Tropical Diseases
- WASH and health working together: a 'how-to' guide for neglected tropical disease programmes, second edition
- Trichiasis surgery for trachoma (3rd edition)
- Safety in administering medicines for neglected tropical diseases

Resource Materials from the International Trachoma Initiative (ITI)

Available from: www.trachoma.org

- Height- and Age-Based Dosing for Azithromycin: POS and Tablets
- Diagram on Decision Making for the Antibiotic Treatment of Trachoma

Resources for Supply Chain Management

- Standard operating procedures for supply chain management of health products for neglected tropical diseases amenable to preventive chemotherapy (WHO)
- ITI Supply Chain Management Course, including facilitator guide, participant guide, modular presentations, and group exercises (available upon request)

World Health Assembly Resolution 51.11 on Global Elimination of Blinding Trachoma

The Fifty-first World Health Assembly,

Recalling resolutions WHA22.29, WHA25.55 and WHA28.54 on the prevention of blindness, and WHA45.10 on disability prevention and rehabilitation;

Aware of previous efforts and progress made in the global fight against infectious eye diseases, in particular trachoma;

Noting that blinding trachoma still constitutes a serious public health problem amongst the poorest populations in 46 endemic countries;

Concerned that there are at present some 146 million active cases of the disease, mainly among children and women and that, in addition, almost six million people are blind or visually disabled as a result of trachoma;

Recognizing the need for sustainable community-based action — including surgery for inturned eyelids, antibiotics use, facial cleanliness and environmental improvement (the SAFE strategy) — for the elimination of blinding trachoma in the remaining endemic countries;

Encouraged by recent progress towards simplified assessment and enhanced management of the disease, including large-scale preventive measures, particularly for vulnerable groups;

Noting with satisfaction the recent establishment of the WHO alliance for the global elimination of trachoma, comprising certain collaborating nongovernmental organizations and foundations and other interested parties,

1. CALLS ON Member States:

(1) to apply the new methods for the rapid assessment and mapping of blinding trachoma in the remaining endemic areas;

(2) to implement, as required, the strategy - including surgery for inturned eyelids, antibiotics use, facial cleanliness and environmental improvement (the SAFE strategy) - for the elimination of blinding trachoma;

(3) to collaborate in the WHO alliance for the global elimination of trachoma and its network of interested parties for the global coordination of action and specific support;

(4) to consider all possible intersectoral approaches for community development in endemic areas, particularly for greater access to clean water and basic sanitation for the populations concerned;

2. REQUESTS the Director-General:

(1) to intensify the cooperation needed for the elimination of blinding trachoma with Member States in which the disease is endemic;

(2) further to refine the components of the SAFE strategy for trachoma elimination, particularly through operational research, and by considering potential antibiotic or other treatment schemes for safe large-scale application;

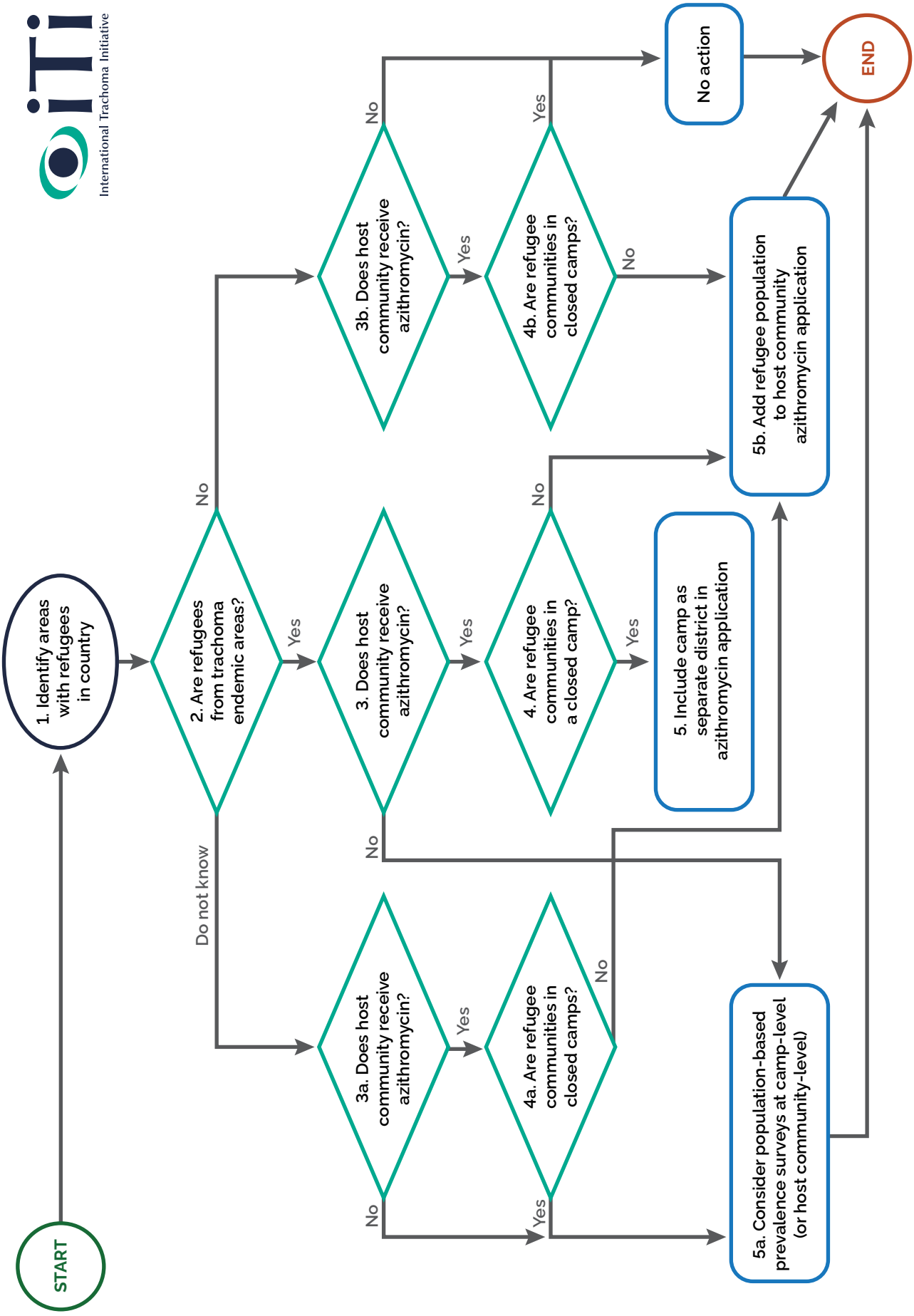
(3) to strengthen interagency collaboration, particularly with UNICEF and the World Bank, for the mobilization of the necessary global support;

(4) to facilitate the mobilization of extrabudgetary funds;

(5) to report on progress, as appropriate, to the Executive Board and the Health Assembly.

(Tenth plenary meeting, 16 May 1998 - Committee A, fourth report)

Flow chart to determine inclusion of refugee communities in annual azithromycin applications for trachoma MDAs



Terminology:

Refugee Camp: In the context of refugee communities, a refugee camp "...is any purpose-built, planned and managed location or spontaneous settlement where refugees are accommodated and receive assistance and services from government and humanitarian agencies. The defining characteristic of a camp... is some degree of limitation on the rights and freedoms of refugees, such as their ability to move freely, choose where to live, work or open a business, cultivate land or access protection and services."
Source: The office of the United Nations High Commissioner for Refugees (UNHCR) Policy on Alternatives to Camps, accessed online, https://bit.ly/2thNNLK

District: The appropriate program implementation unit in the country requesting azithromycin for trachoma MDAs.

Host community: The district (or trachoma program implementation unit) that hosts the refugee community, either in formal camp settings or in informal settlements.

Internally displaced persons: Internally displaced persons (IDPs) are "persons or groups of persons who have been forced or obliged to flee or to leave their homes or places of habitual residence, in particular as a result of or in order to avoid the effects of armed conflict, situations of generalized violence, violations of human rights or natural or human-made disasters, and who have not crossed an internationally recognized state border." This is a descriptive definition and not legally binding for any party.
Source: The office of the United Nations High Commissioner for Refugees (UNHCR) Emergency Handbook, accessed online, https://bit.ly/2t68zic

Refugees: Article 1(A)(2) of the 1951 Convention, as amended by its 1967 Protocol, defines a refugee as someone who: "owing to well-founded fear of being persecuted for reasons of race, religion, nationality, membership of a particular social group or political opinion, is outside the country of his nationality and is unable or, owing to such fear, is unwilling to avail himself of the protection of that country; or who, not having a nationality and being outside the country of his former habitual residence, is unable or, owing to such fear, is unwilling to return to it. In the case of a person who has more than one nationality, the term "the country of his nationality" shall mean each of the countries of which he is a national, and a person shall not be deemed to be lacking the protection of the country of his nationality if, without any valid reason based on well-founded fear, he has not availed himself of the protection of one of the countries of which he is a national."
Source: Convention relating to the Status of Refugees, United Nations Human Rights, Office of the High Commissioner, accessed online, https://bit.ly/2MUkk3n

Request: Annual application for azithromycin from trachoma endemic countries reviewed by the Trachoma Expert Committee during bi-annual meetings organized by the International Trachoma Initiative.

Safety Reporting Requirements for Zithromax® Donation and Safety Reporting Requirements for Azithromycin Donation

1. Introduction

1.1 Pfizer has a legal and corporate responsibility to comply with applicable regulations governing the collection and reporting of potential Adverse Events ("AE(s)"), At Risk Scenarios ("ARS(s)"), Unexpected Therapeutic Effects ("UTEs"), and Product Quality Complaints ("PQC(s)") related to the use of Pfizer drug products, including azithromycin.

1.2 The Ministry of Health (MOH) shall ensure that all program staff and implementing partners involved in the trachoma elimination program comply with requirements as outlined in this Annex A.

2. Definitions

2.1 Adverse Event: Any untoward medical occurrence in a subject, patient, or consumer administered a Pfizer product. All reports of Adverse Events should be forwarded, regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and regardless of the event being mentioned in the product label/instructions.

Adverse Events include, but are not limited to:

- Abnormal test findings
- Clinically significant signs and symptoms
- Changes in physical examination findings
- Progression/worsening of underlying disease
- Allergic reactions
- Lack efficacy
- Drug abuse
- Drug dependency
- Drug withdrawal
- Hospitalization
- Death
- Any suspected transmission of an infectious agent via a Pfizer product (e.g., a physician reports that a patient developed an eye infection after using a Pfizer ophthalmic product)
- Any Undesirable Effect (i.e., any adverse reaction attributable to the normal or reasonably foreseeable use of a cosmetic product)
- Interactions with other drugs or with food

2.2 At Risk Scenario (ARS): Circumstances that may increase the patient's/consumer's risk of developing adverse events. These circumstances must be reported regardless of whether they are associated with an AE.

These circumstances include:

- Medication errors
- Exposure during pregnancy
- Exposure during breastfeeding
- Overdose
- Misuse
- Extravasation
- Occupational exposure
- Off-label use

2.3 Unexpected Therapeutic Effect ("UTE"): A beneficial therapeutic effect of a Product aside from the use for which it had been given.

2.4 Product Quality Complaint (PQC): Is any written, electronic or oral communication that alleges deficiencies related to the quality or physical properties, condition, package insert and/or packaging of a Pfizer product.

3. Reporting Process

3.1 Reporting Time-Frames: If Ministry of Health personnel become aware of potential AE, ARS, UTE, or PQC reports that may be associated with azithromycin, they shall inform Pfizer within one (1) business day, or three (3) calendar days, (whichever is shorter), of becoming aware of the AE, ARS, UTE, or PQC report. Reporting responsibilities are the same for all AEs, irrespective of the listedness, seriousness of the event or whether or not it was caused by the Product. All ARS, UTEs and PQCs should be reported, whether or not there is an associated AE.

3.2 Case Documentation: The MOH shall document all potential AEs, ARSs, UTEs, and PQCs in accordance with Pfizer directed instructions (including, where possible, the contact information e.g. name, address, and phone number of the reporter, and whether consent has been given by the reporter to be re-contacted by Pfizer if further information is required.) and will maintain a record of each AE/ARS report and PQC received and reported to Pfizer. These records shall be provided to Pfizer on request.

3.3 AEs, ARSs UTEs and PQCs should be reported to the contacts identified in Table 1 below, which may be updated in writing by the Task Force for Global Health and Global Health Solutions (GHS) from time to time. Reports should be sent to the appropriate Pfizer safety group.

3.4 In forwarding AE, ARS, UTE, or PQC reports on azithromycin to Pfizer, The MOH shall comply with all applicable privacy and data protection laws and regulations on the protection of individuals with regard to the processing of personal data and the free movement of such data. "Personal Data" means information that can be used by itself or in combination with other available information to identify a specific individual.

Obligations of the International Trachoma Initiative and the Ministry of Health

The following is an excerpt from the Memorandum of Understanding, which outlines the obligations of the International Trachoma Initiative and the Ministry of Health:

1. **Obligations of ITI:** Global Health Solutions, Inc. ("GHS") is a supporting organization of TFGH. Through GHS, ITI agrees to provide MOH with **up to {insert number} treatments** of the antibiotic azithromycin, donated by Pfizer to GHS or another entity for the exclusive purpose of trachoma control in approved districts in 2024. **Please note that {insert number or "all"} of these treatments are approved with contingency, requiring that a specified condition be met prior to the shipment of azithromycin (see Addendum {insert II.a and/or II.b and/or II.c}).**

   These treatments are valued at **{insert amount} USD**. This will ensure treatments **for up to {insert number} people** in 2024. Final quantities of Zithromax® shipped may be reduced by ITI, based on changed circumstances during the year, and in-country inventory.

   District names and quantities of treatments approved by the Trachoma Expert Committee ("TEC") for distribution in 2024 are found in the Addendum. Any subsequent changes to the approved quantities listed in the Addendum will be communicated to MOH by means of an Amendment to this MOU.

   ITI is under no obligation to replace any azithromycin to the extent it has been compromised as a direct result of a failure by the MOH to comply with the requirements set forth in this MOU for the storage, handling, distribution, and disposal of azithromycin.

   Throughout the term of this three year MOU, ITI will send the MOH an updated Addendum for each calendar year which will outline the details of the drug donation.

2. **Obligations of MOH:** MOH agrees to abide by the following parameters:
   - **a.** Ensure all required Permits, regulatory approvals, and/or waivers and associated import documentation are obtained. Provide copies of these documents or authorizations upon ITI's request.
   - **b.** Ensure that azithromycin is not used for research purposes without the prior, full, written approval of ITI or TEC.
   - **c.** Ensure free entry of azithromycin into the country and into the approved districts without imposing customs duty or tax or other costs. Any associated fees, including, but not limited to, clearing agent fees, customs clearance fees, taxes, documentation fees, demurrage fees, as well as in-country insurance, warehousing, and inventory management are the responsibility of the MOH.
   - **d.** Ensure that azithromycin is distributed only in the districts for which the donation is expressly approved in the Addendum below.
   - **e.** Obtain the necessary financial and human resources to support the distribution of the donated azithromycin.
   - **f.** Implement the full SAFE strategy in the districts in which the azithromycin distributions occur.
   - **g.** Exclude children under 6 months of age from receiving azithromycin during distribution campaigns.
   - **h.** Ensure that product safety monitoring and reporting processes are in place. If the Ministry of Health and/or Implementing Partners become aware of potential Adverse Events ("AE(s)"), At Risk Scenarios ("ARS(s)"), Unexpected Therapeutic Effects ("UTEs"), and Product Quality Complaints ("PQC(s)") that may be associated with azithromycin, they will inform Pfizer through the designated Pfizer regional offices listed in the contact list on Table 1 in accordance with the procedures for AE, ARS, UTE and PQC reporting included in Annex A of this MOU.

i. Ensure that azithromycin is used only for the control of trachoma as mutually agreed between MOH and ITI, and is not transferred or sold in exchange for money, property or services. It is the intent and agreement of the parties that all donated azithromycin will be distributed in a non-commercial fashion.

j. The collection, storage, handling, transportation, movement, disposal, and destruction of all expired azithromycin donated pursuant to this MOU shall be the responsibility of MOH in compliance with the WHO guidance on the disposal of unused medicine, any Pfizer guidance as may be provided, and in accordance with all applicable Laws. "Laws" means all applicable laws, directives, rules, ordinances, codes, guidelines, regulations, governmental, administrative, or judicial orders or decrees or other legal requirements of any kind or nature, including those related to the protection of the environment, natural resources, human health, and hazardous substances. Provide copies of certificates of destruction or disposal upon ITI's request.

k. Ensure that there are adequate controls in place to enable the safe, secure, and lawful transport, storage, administration, use, and disposal of azithromycin and its packaging and to prevent spoilage, diversion, loss, or theft of azithromycin. MOH shall notify Pfizer by email immediately (i.e. within one (1) day) with follow up in writing within five (5) business days if at any time MOH believes or becomes aware that any of azithromycin has been stolen, diverted, tampered with, substituted, resold, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. The notice shall provide all information relating to azithromycin diversion, including but not limited to, detailed information including the date, time, location, number, batch/lot number(s), expiration date, circumstances, and contact person(s) information.

l. Cooperate with ITI, Pfizer, TEC and their respective affiliated entities and representatives as reasonably required to accomplish the objectives of this MOU. MOH will work with ITI to develop forecasts that will be used to guide the manufacture, shipment, and distribution of azithromycin, and will cooperate with third party consultants as identified by ITI on efforts to audit and improve the supply chain for the shipment and distribution of azithromycin.

m. Ensure that mass administrations of azithromycin donated by Pfizer are not conducted concurrently with mass administrations of azithromycin or oral azithromycin purchased or donated from a different source. Azithromycin donated by Pfizer must be assigned its own stock keeping unit (SKU) and must be stored separately from generic azithromycin from other sources to prevent the Pfizer-donated product from being used by the general health system.

n. Ensure that azithromycin left in the country after country-wide cessation of MDA will be used for the sole purpose of supporting the Trachoma Program's mission of eliminating blinding trachoma through the implementation of the SAFE Strategy (e.g., post-surgical treatment and targeted treatment during surveys).

3. **Reporting Requirements:** MOH agrees to submit to ITI reports of progress in the format provided by ITI, including:

a. The number of persons treated with azithromycin.

b. Results of trachoma prevalence surveys, both baseline and impact.

c. Implementation of activities relating to surgery, facial cleanliness, and environmental improvements.

d. Any changes to district names, boundaries, and populations.

e. Confirmation of receipt of shipments of azithromycin within seven days of arrival at Central Medical Stores

f. Azithromycin stock-on-hand, quantities, batch/lot numbers, expiry dates, and the precise location of the stock.

MOH acknowledges and agrees that ITI will enter the data reported by countries into the GET 2020 Database, a database shared between ITI and the World Health Organization. ITI may also provide these reports and/or information derived from these reports to Pfizer and to other organizations in ITI's reasonable discretion.

Reports are to be submitted to ITI as follows:

Reporting Period	Due Date
1 January – 31 December 2025	2 March 2026
1 January – 31 December 2026	1 March 2027
1 January – 31 December 2027	1 March 2028

Non-compliance to the terms of obligation and reporting requirements can result in a delayed shipment, reduced azithromycin quantities, and/or exclusion from future donations.

4. **Requirements of Funding and Reception of Donated Products:** Azithromycin donations are to be used solely for activities as agreed upon by ITI and MOH. No portion of the donated azithromycin may be used for the support, direct or indirect, of any acts of violence or terrorism or for any organization engaged in or supporting such acts.
5. **Global Trade Control Laws:** Activities covered by this MOU may be subject to Global Trade Control Laws. MOH will perform the activities and its responsibilities under this Agreement in full compliance with all applicable Global Trade Control Laws listed in Annex C.
6. **Requirements of Funding and Reception of Donated Products:** Zithromax® donations are to be used solely for activities as agreed upon by ITI and MOH. No portion of the donated Zithromax® may be used for the support, direct or indirect, of any acts of violence or terrorism or for any organization engaged in or supporting such acts.
7. **Obligations Following Termination:** In the event of early termination, MOH shall (a) continue to honor the obligations concerning the use of donated Zithromax® received by MOH prior to termination and the submission of reports set forth in paragraphs 3 and 4 above, and (b) if requested by ITI, return any quantities of donated Zithromax® that have not yet been distributed.

Shipment Calculation Tool

Country	Name
Approved for MDA (A)	1,262,088
Approved for Surgery or Research (B)	6,078
Reserve (C)	
Subtotal (D=A+B+C)	1,268,166
Reduction % (E)*	0.2
Reduction (F=(A+C)*E)	252,418
Total (G=D-F)	**1,015,748**

*Shipment reduction is contingent upon TEC recommendations concerning supply.

Planned Shipment	POS	Tablets	Total
Ratio Requested (H)	0.20	0.80	1.00
Dosage (I=mL POS; J= # of Tablets)	10	3.8	
Treatments Needed (K=H*(G-B))	201,935	813,815	1,015,750
In Country Inventory Reported (L)	1,518	10,731	12,249
Planned Shipment (M=K-L)	**200,417**	**803,084**	**1,003,501**

Actual Shipment	POS	Tablets	Total
Bottles (N=M/30/I POS; O=M/500/J Tablets; round up for a full case)	66,816	6,144	72,960
Cases (P=N/48 POS; Q=O/24 Tablets)	1,392	256	1,648
Pallets (P/32 for POS and Q/54 for Tablets)	43.5	4.7	48.2
Shipment Ratio	0.20	0.80	1.00
Treatments (N*30/I for POS and O*500/J for Tablets)	**200,448**	**804,864**	**1,005,312**

This shipment will include treatments for:	
District 1	215,645
District 2	131,283
District 3	275,891
District 4	301,549
District 5	337,720
Total Approved	**1,262,088**

Azithromycin Contact List
(Country Name) 2025 Shipment

ITI Contact:

NAME
Position
The Task Force for Global Health
325 Swanton Way
Decatur, GA 30030 USA
Tel:
Fax:
Email:

Country Contact:

NAME
Position
Address
Tel:
Fax:
Email:

Proforma Information :

Donee:

NAME
Position
Global Health Solutions, Inc.
325 Swanton Way
Decatur, GA 30030 USA
Tel:
Fax:
Email:

Consign To:

NAME
Position
Address
Tel:
Fax:
Email:

Deliver To:

NAME
Position
Address
Tel:
Fax:
Email:

Importer of Record:

NAME
Position
Address
Tel:
Fax:
Email:

Notify Contacts:

NAME
Position
Address
Tel:
Fax:
Email:

NAME
Position
Address
Tel:
Fax:
Email:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Date

Name
Global Health Solutions, Inc.
325 Swanton Avenue
Decatur, GA 30030

Re: Letter of Donation – (**Country of Destination)**

Dear Name:

Pfizer Inc. is pleased to collaborate with Global Health Solutions and the **(Country)** Ministry of Health and Social Welfare in the efforts to eliminate blinding trachoma as a public health threat in **(Country)**. As such, by this letter, we would like to notify you that Pfizer Inc. is donating the following to Global Health Solutions:

- **(Quantity)** bottles, 1200mg of Zithromax® (azithromycin) powder oral suspension (cherry flavor), at 48 bottles per case **(Quantity of full cases)**, with 144 plastic dosing cups per case; and

- **(Quantity)** bottles, 500-count, of azithromycin 250mg tablets, at 24 bottles per case **(Quantity of full cases)**.

The donated product has no commercial value and cannot be sold. It is a donation for humanitarian purposes. We advise that it is for exclusive use in the treatment of *Chlamydia trachomatis* (trachoma) in **(Country)**. As you know, the product has been approved in **(Country**) for this program and meets the criteria for duty-free entry and exemption of all fees related to commercial processing. By accepting the donation, you warrant that there has been no change in the organization's 501c3 status or its classification as a public charity and not a private foundation.

On your behalf, the Ministry of Health's Medical Stores Department (MSD) will assist with clearance, transport, and central storage. If you have questions, please work with Name (Name @pfizer.com).

We wish you the best of success in this endeavor and look forward to working with you.

Sincerely,

Name
Senior Manager, Global Donations Programme

www.pfizer.com

Annex 9: Pro Forma Invoice

PFIZER SERVICE COMPANY BV
Hoge Wei 10
1930 ZAVENTEM
BELGIUM

Hyperion Code:005923
VAT:BE0478242365

PROFORMA INVOICE

Invoice No.: 31798416
Billing Date: 10-Jul-2024
Document Date: 10-Jul-2024

Sold-To - 2000001778

GLOBAL HEALTH SOLUTIONS INC
325 SWANTON WAY
UNITED STATES OF AMERICA
DECATUR GA 30030

Ship-To - 2001002143

MEDICAL STORES LIMITED
NATIONAL TRACHOMA PROGRAM

Notify Party -

Ship From

Essers LSP Temp. Sensitive
Transportlaan 4
3600 GENK
BELGIUM

Sales Order No.
5096903886

Customer Order No.
2024 Country #1

Shipment No.

Incoterms
CIP

Terms of Payment
No Charge

Letter of Credit

Mode of Transport
Air

Vessel/Flight No.

Port of Export

Port of Dest. (Vessel, Air Only)

Ship From Country
Belgium

Shipping Marks

Item	Material Number / Material Description	Quantity / Customs Tariff Code	Unit Price / Country of Origin / Region	Value in USD
000010	F000061921 Azithromycin 250mg TFC 1x500 PBTL USP	2.220 EA HS Origin : 3004.20.00 HS Destination: 3004.20	500,00000 / EA India	1.110.000,00

Batch:
Exp Date: Manuf Date:

Donation — For Customs Only

Export Control License NLR_NO LICENSE REQUIRED — Not On Control List

DONATION MATERIAL - QUANTITY OF TABS IS STATED IN BOTTLES

Remit To:
Name of bank: Citibank Dublin
Bank Account: 27190863
Bank number: 990051
SWIFT code: CITIIE2X
IBAN: IE68CITI99005127190863

Annex 9: Pro Forma Invoice

PFIZER SERVICE COMPANY BV
Hoge Wei 10
1930 ZAVENTEM
BELGIUM

PROFORMA INVOICE

Invoice No.:	31798416
Billing Date:	10-Jul-2024
Document Date:	10-Jul-2024

000100	F000129372	627 CS	273,60000 / CS	171.547,20

ZITHROMAX 1200mg POS 48x1 BTL

HS Origin : 3004.20.00
HS Destination: 3004.20

Italy

Batch:

Exp Date: Manuf Date:

Donation For Customs Only

Export Control License NLR_NO LICENSE REQUIRED Not On Control List

DONATION MATERIAL - QUANTITY OF POS IS STATED IN CASES OF 48 BOTTLES

TOTAL ITEM VALUE	0,00	%	0,00
VAT	0,00	%	0,00
VAT			0,00
TOTAL AMOUNT			0,00
FREE ITEMS (INCLUDE IN VFC)			5.459.241,60
TOTAL VALUE FOR CUST			5.459.241,60

These commodities, technology or software were exported in accordance with applicable export control laws. Prior to any further shipments or transfers, authorization from relevant governmental entities may be required.

Article 146,1, a) Council Directive 2006/112/EC - VAT-exempt export of goods
It is hereby certified that this invoice shows the actual price of the goods described, that no other invoice has been issued, and that all particulars are true and correct. Supply of Product shown above during the month per the date mentioned above.

Donee of Record:
Chief Operating Officer
Global Health Solutions, Inc
325 Swanton Way
Decatur, GA 30030 USA

Consign To:
Permanent Secretary- Health Services

AWB NUMBER

Shipper's Name and Address PFIZER SERVICE COMPANY BV HOGE WEI 10 ZAVENTEM 1930 BE E EORI No.:	Shipper's Account Number
Not Negotiable **Air Waybill** Issued by AIRLINE CARGO OFFICE (2ND FLOOR) INT. AIRPORT, (COUNTRY)	Copies 1, 2 and 3 of this Air Waybill are originals and have the same validity.
Consignee's Name and Address THE PERMANENT SECRETARY MINISTRY OF HEALTH	Consignee's Account Number
Issuing Carrier's Agent Name and City DHL GLOBAL FORWARDING (BELGIUM) NV/SA BRU	Accounting Information
Agent's IATA Code	Account No
Airport of Departure (Addr. of First Carrier) and Requested Routing	Reference Number: C2401592440 / Optional Shipping Information

To	By First Carrier	Routing and Destination	to	by	to	by	Currency	CHGS Code	WT/VAL	Other	Declared Value for Carriage	Declared Value for Customs
DSS	AB		DAR	AB			EUR	PP	X	X	NVD	NCV

Airport of Destination	Requested Flight/Date	Amount of Insurance	INSURANCE
COUNTRY	AB2611/121/AB26	XXX	INSURANCE - If carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures in box marked "amount of insurance".

Handling Information SPX KC BE/RA/00106-01-COVID 19 -KEEP BETWEEN +15 & + 25 DEGREES CELSIUS-24H EMERGENCY PHONE+32495580211 / DA6 / BE/RA/00106-01

SCI: X

No. of Pieces RCP	Gross Weight	kg lb	Rate Class / Commodity Item No.	Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)
121	18520.0	K	Q	30191.0	3.00	90573.00	PHARMACEUTICALS - NOT RESTRICTED SRN: 8113625225 , 8113830626 , 8113756800 , 9771653442 , 9771653440 , 9771653441 CRF: 3328847 , 3328722 , 3328755 EXA:15495KG + 3025KG BLA = 18520KG VOL 181.145 M3 121 SLAC
121	18520.0					90573.00	

Telegrams:
Telephone:
Email:

Prepaid	Weight Charge	Collect
90573.00		
	Valuation Charge	
	Tax	
	Total Other Charges Due Agent	
	Total Other Charges Due Carrier	
22710.25		
Total Prepaid		Total Collect
113283.25		
Currency Conversion Rates		CC Charges in Dest. Currency
For Carrier's use only at Destination	Charges at Destination	Total Collect Charges

Other Charges

HNC	AIRLINE AIRFREIGHT SURCHARGE	7.00
HTC	AIRLINE AIRFREIGHT SURCHARGE	60.00
HYC	FUEL SURCHARGE	22643.25

Shipper certifies that the particulars on the face hereof are correct and that insofar as any part of the consignment contains dangerous goods, such part is properly described by name and is in proper condition for carriage by air according to the applicable Dangerous Goods Regulations.

AS AGENT

JULIEN CAMPS

Signature of Shipper or his Agent

DHL Global Forwarding (Belgium) NV/SA
Bedrijvenzone Machelen Cargo 830
B-1830 Machelen
Phone 32-2/752 02 11
Ent. nummer: BE0400815841

AS AGENT OF: ALLIED AIR LIMITED

05-Aug-24 — MACHELEN — DHL GLOBAL FORWARDING (BELGIUM) NV/

Executed on (date) — at (place) — Signature of Issuing Carrier or its Agent

AWB NUMBER

AZITHROMYCIN RECEIPT CONFIRMATION FORM

From: (country receiving the shipment) _____ **Shipment arrival date:** _____

To: ITI Supply Chain Manager **Delivery date at the CMS:** _____

This is to acknowledge that we have received the following azithromycin products on: _____

(date) **Total number of pallets sent/received:** _____ / _____

Product Description	Quantity received in good condition (in bottles)	Total Quantity shipped (in bottles)	Quantity taken for sampling (in bottles)	Quantity damaged/lost (in bottles)	Current storage location
1. Tablets					
2. Powder for Oral Suspension (POS)					

Note on sampling taken for testing and analysis: (Provide batch numbers and quantity taken for sampling)

Note on the damaged and lost products:

Prepared by: _____ **Approved by:** _____

Stamp or seal:

Azithromycin Allocation Schedule

Region	District	Eligible Population *a*	Gross Required amount		Stock on hand		Shipment amount	
			Tablets (Bottles) $b = \frac{a \times 0.8 \times 3}{500^*}$	POS (Bottles) $c = \frac{a \times 0.2 \times 7.5}{30^*}$	Tablets (Bottles) *d*	POS (Bottles) *e*	Tablets (In cartons) $f = \frac{b - d}{24^{**}}$	POS (In cartons) $g = \frac{c - e}{48^{**}}$

*Note: Quantities are based on the current bottle size **Number of bottles of azithromycin per carton

Azithromycin for MDA

Name of Country:
Date of Report:
Name of Person Providing the Report:

TAB 1 - Azithromycin for MDA - Inventory Report

Thank you for not entering any data in the section in yellow. These values are calculated automatically.	
Total Usable Treatments	
Total Treatment Loss	
Total Expired	
Total Wasted	
Total Unusable	
Total Losses/Adjusts	

Return email for inventory report:

				Available Usable Stock			Expiry Dates for Usable Stock		Expired Drugs		Wasted		Unusable		Other Losses/Adjustments		Total Loss	
District	Storage Location	Date of Physical Inventory	Batch #	Tablets (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)	Tablets (Bottles)	POS (Bottles)
		DD-MON-YYYY		Sealed	Opened	Sealed	DD-MON-YYYY	DD-MON-YYYY										
	TOTAL																	

Explanation of Terms:
Available Usable Stock- This is stock that still has shelf life and can be distributed.
Wastage- This is the number of azithromycin bottles that were wasted during treatment.
Unusable- This is the azithromycin in damaged bottles.
Damage includes those that have missing/damaged labels, stickiness or discoloration on tablets or any other indication that the products may not usable.
Expired- This is the number of azithromycin bottles that are past their expiry date, and therefore may not be used.
Losses- This is the quantity of azithromycin removed from the system for any reason other than consumption (theft, for example).
An explanation is required noting either theft or another clear explanation for the cause of loss.
Adjustment- This is a record that is used for azithromycin transfer between locations or a record to be made when differences arise between inventory count & recorded balance.

Comments:

Azithromycin for Surgery

Name of Country:
Date of Report:
Name of Person Providing the Report:

TAB 2 - Azithromycin for Surgery - Inventory Report

Thank you for not entering any data in the section in yellow. These values are calculated automatically.	
Total Usable Treatments	
Total Treatment Loss	
Total Expired	
Total Wasted	
Total Unusable	
Total Losses/Adj	

Return email for inventory report:

				Available Usable Stock		Expiry Dates for Usable Stock	Expired Drugs	Wasted	Unusable	Other Losses/Adjustments	Total Loss
District	Storage Location	Date of Physical Inventory	Batch #	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)	Tablets (Bottles)
		DD-MON-YYYY		Sealed	Opened	DD-MON-YYYY					
	TOTAL										

Explanation of Terms:
Available Usable Stock- This is stock that still has shelf life and can be distributed.
Wastage- This is the number of azithromycin bottles that were wasted during treatment.
Unusable- This is the azithromycin in damaged bottles.
Damage includes those that have missing/damaged labels, stickiness or discoloration on tablets or any other indication that the products may not usable.
Expired- This is the number of azithromycin bottles that are past their expiry date, and therefore may not be used.
Losses- This is the quantity of azithromycin removed from the system for any reason other than consumption (theft, for example).
An explanation is required noting either theft or another clear explanation for the cause of loss.
Adjustment- This is a record that is used for azithromycin transfer between locations or a record to be made when differences arise between inventory count & recorded balance.

Comments:

STOCK CARD

Location_____ Description_____ Batch No._____

Store No._____ Unit_____ Expiry Date_____

Date	Quantity Received	Origin	Quantity Issued	Destination	Quantity on hand (Balance)	Waybill/Delivery Note/ Stock Requisition Form No.	Signature	Remarks
New Opening Balance/Balance Carried forward								
Balance to be carried forward								

Transfer Form

Serial No._____ **Date:** _____

Origin:_____ **Destination:**_____

Name and address of the carrier/person responsible:

Transfer Item list: (to be filled at the origin)

Item	**# of cartons**	**# of bottles**	**Total quantity shipped in good condition (in bottles)**
Azithromycin tablets			
Azithromycin POS			

Issuer:_____ **Carrier:**_____

Issuer Signature:_____ **Carrier Signature:**_____

(The following section should be filled out at the destination)

List of quantities received in good condition:

Item	**# of cartons**	**# of bottles**	**Total quantity shipped in good condition (in bottles)**	**Damaged/loss (in bottles)**	**Total quantity received in good condition (in bottles)**
Azithromycin tablets					
Azithromycin POS					

Note for damaged /lost quantity (if any):

Receiver:_____ **Carrier:**_____

Receiver Signature:_____ **Carrier Signature:**_____

2025 Trachoma Elimination Monitoring Form – Data for 2024

Every year, countries are asked to report on trachoma activities conducted the previous year at the district level. Below is information requested for each district.

Geography & Population			
Region	District	Sub-district	Total 2024 Population Targeted

Survey Data							
Year of Current Survey	Current TF % (1-9 yrs)	Current TT%	TT Age Group and Sex	Source	Current *Ct* prevalence (%)	Current Sero-prevalence (%)	Current Sero conversion Rate (SCR)

Surgery		
2023 Number of TT Cases Managed		
TT Cases Managed: Women and Girls	TT Cases Managed: Men and Boys	Total TT Cases Managed (both genders combined)

Antibiotics														
2024 Number of Persons Targeted for Treatment	2024 Month of MDA	2024 Number of Persons Treated with Azithromycin Tablets			2024 Number of Persons Treated with Azithromycin Pediatric Oral Suspension			2024 Number of Persons Treated with Tetracycline Eye Ointment			2024 Number of Persons Treated with Azythromycin Eye Drops			2024 Total Number of Persons Treated	Treatment Coverage % in 2024 (treated/targeted)
		Women and Girls Treated	Men and Boys Treated	Total Treated (both genders combined)	Women and Girls Treated	Men and Boys Treated	Total Treated (both genders combined)	Women and Girls Treated	Men and Boys Treated	Total Treated (both genders combined)	Women and Girls Treated	Men and Boys Treated	Total Treated (both genders combined)		

Facial Cleanliness							Environmental Improvement							
Methods of Delivery of F - TYPE "X" FOR THOSE THAT APPLY							Methods of Delivery of E - TYPE "X" FOR THOSE THAT APPLY							Notes/Comments
At time of MDA	School-based	Radio messages and/or other mass media	Village health worker or equivalent	Primary healthcare	Other	None	Latrine construction by NTTF member	Latrine construction by other stakeholders	Water point construction by NTTF member	Water point construction by other stakeholders	Community-led total sanitation	Other	None	

www.trachoma.org

330 West Ponce de Leon Avenue
Decatur, Georgia 30030
USA

+1.404.371.0466 | Fax: +1-404-371-1087
communications@taskforce.org