

Zithromax[®] Management Guide

2019

How to successfully apply for, administer, and manage the Zithromax[®] donation for trachoma elimination





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: Two Community Drug Distributors (CDDs), Alemetu Metalign and Terengku Mulat, are conducting a Mass Drug Administration (MDA) with Zithromax® to eliminate trachoma in North Mecha Woreda, Amhara Region, Ethiopia. Endeshaw Kifle, a volunteer, measures the next child against the height-based dosing pole. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

Copyright © 2019 by International Trachoma Initiative. Version 2: Updates August 2020

This book or any portion thereof may not be reproduced without the express permission of the publisher.

Editions prior to 2019 should no longer be referenced and should be destroyed.

Acknowledgments

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

David Addiss
Birgit Bolton
Fernanda Debellian
Paul Emerson
PJ Hooper
Julie Jenson
Carla Johnson
Yen Kim
Genevieve LaCon
Chad MacArthur
Nicholas Olobio
Sumon Ray
Najwa Sampson
Girija Sankar
Moumine Yaro

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 whose example is the basis of 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
© 2019 ITI

International Trachoma Initiative
330 West Ponce de Leon Avenue
Decatur, GA 30030

Tel: +1-404-371-0466
Fax: +1-404-371-1087

Designed by:
Resonance Marketing
www.withresonance.com

Printed by:
Elanders USA
www.elandersamericas.com



A Community Drug Distributor (CDD) holding a dosing pole and a bottle of Zithromax® tablets during a Mass Drug Administration (MDA) in Sokoto State, Nigeria. Nigeria is one of the most high burden trachoma-endemic countries in the world. *Photo credit: Sumon Ray for the International Trachoma Initiative.*

List of Acronyms

AE — Adverse Event

CDD — Community Drug Distributor

CO — Corneal Opacity

ELC — Pfizer European Logistics Center

FEFO — First Expiry - First Out

FIFO — First In, First Out

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

ICTC — International Coalition for Trachoma Control

ITI — International Trachoma Initiative

LMIS — Logistics Management Information System

MDA — Mass Drug Administration

MOH — Ministry of Health

MOU — Memorandum of Understanding

NPC — National Program Coordinator

NTD — Neglected Tropical Disease

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

TF — Trachomatous Inflammation, Follicular

TI — Trachomatous Inflammation, Intense

TEMF — Trachoma Elimination Monitoring Form

TEO — Tetracycline Eye Ointment

TS — Trachomatous conjunctival Scarring

TT — Trachomatous Trichiasis

WHO — World Health Organization

ZMG — Zithromax® Management Guide



Embet Belachew, aged 7, is receiving her dose of Zithromax® in the form of oral suspension in North Mecha Woreda, Amhara Region, Ethiopia. An annual dose of Zithromax® 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 have most of the infection and it is important to include them in the distribution. 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 Director

In 1998, we started with a nearly impossible goal: the global elimination of an ancient scourge. Through my work, I've had the opportunity to witness firsthand the phenomenal progress achieved over the last 20 years, as efforts shifted from small-scale projects to a truly global programme. With the generous donation of Zithromax®, Pfizer have catalyzed the programme and the number of people receiving donated drug has increased from 100,000 people receiving treatments in the first year to 100 million receiving treatments annually. This scale-up has offered us many lessons in the management and distribution of Zithromax®, which are reflected in the new Zithromax® Management Guide (ZMG).

The ZMG is designed for all those involved in trachoma elimination programs using donated Zithromax®, and replaces the previous Zithromax® in the Elimination of Blinding Trachoma: A Program Manager's Guide (2010) which was specifically targeted to Ministry of Health personnel. In this version, we have simplified the guidance presented, and avoided duplication of materials already developed by the International Coalition for Trachoma Control (ICTC) and World Health Organization (WHO).

The most important change presented in this ZMG is the dose of Zithromax® offered to children, with the goal of enhancing the safety, ease, and acceptability of Zithromax® administration. The age and height for children to be offered Powder for Oral Suspension (POS; syrup) has now increased. Previously, the age range to be offered POS was 6 months to 5 years (60 months); now, we recommend that POS be offered to children aged 6 months to 7 years (84 months). Previously, children 74 to 120 centimeters in height qualified for 1 or 2 tablets; now, we have removed the 1- and 2-tablet dosing altogether from the tablet dosing pole and recommend all participants shorter than 120 centimeters receive POS (regardless of age).

The guidance in the new ZMG is presented in two sections: one which presents guidance relevant to program managers, planners, and implementers; the other, to 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.

— Paul Emerson, Director, International Trachoma Initiative

Zithromax® Program Management Guide



A Community Drug Distributor (CDD) is preparing Zithromax® Powder for Oral Suspension (POS) during a Mass Drug Administration (MDA) in Malawi. *Photo Credit: Billy Weeks for the International Trachoma Initiative*

Table of Contents

1. Introduction	3
1.1: Trachoma Epidemiology	3
1.2: Purpose of this Guide	4
1.3: SAFE Strategy	5
1.4: The Life Cycle of Trachoma	6
1.5: Trachoma Grading	7
2. Zithromax® Donation Program	9
2.1: Qualifying for Zithromax®	9
2.2: Decision-making for Mass Drug Administration (MDA) with Zithromax®	9
2.3: Application Process	10
2.4: Summary	11
2.5: Zithromax® Application Timeline	12
2.6: Application Review	13
2.7: Memorandum of Understanding (MOU)	14
2.8: Receiving Zithromax®	15
2.9: Annual Reporting Process	15
3. Mass Drug Administration (MDA) Strategy	17
3.1: Donated Zithromax® for Trachoma	17
3.2: Population Eligible for Zithromax®	18
3.3: Exclusion Criteria	19
3.4: Optimal Coverage	19
3.5: Treating Children	20
3.6: Distribution Duration and Frequency	21
3.7: Training Distributors	22
3.8: Community Awareness	25
3.9: Safety of Zithromax®	26
3.10: Reporting Process for Adverse Events (AEs)	27
3.11: Dealing with Rumors and Refusals	28
3.12: Supportive Supervision	29



Gedefaye Metikie has had minor trichiasis (TT) for 3 or 4 years but has put off her surgery until her youngest child is weaned. In the meantime, her oldest daughter Yalemworke Gashaw lovingly epilates the eyelashes rubbing against her mother's eye between her fingernails in North Mecha Woreda, Amhara Region, Ethiopia. Gedefaye is aware that a simple 10–15 minute surgery is available free of charge through the Lions/Carter Center Sightfirst Initiative offered by the Amhara Regional Health Bureau. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

1. Introduction

There are intensive efforts underway to eliminate trachoma as a public health problem globally. 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. Strong partnerships have been developed and there is an excellent understanding of where intervention against trachoma is needed.

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 non-governmental organizations to eliminate trachoma. ITI manages the allocation and distribution of the antibiotic, Zithromax®, donated by Pfizer Inc. (Pfizer), to treat active trachoma infections; and collaborates with partners to implement all other aspects of the WHO-recommended SAFE strategy. ITI mobilizes resources for trachoma elimination programs and provides technical assistance and logistical assistance to partners. Additionally, ITI supports trachoma research, program monitoring and evaluation and develops and strengthens partnerships for implementing the SAFE strategy for disease elimination.

1.1: Trachoma Epidemiology





Photo credit: International Trachoma Initiative

1.2: Purpose of this Guide

This is a revised version of the Zithromax® Program Managers' Guide that was first developed in 2010.

- ▶ This guide is for trachoma program managers and National Trachoma Task Forces in countries participating in the Zithromax® donation program.
- ▶ The guide will assist programs in the planning, implementation, and evaluation of the antibiotic (the "A") component of the SAFE strategy.
- ▶ This revised edition of the Zithromax® Management Guide (ZMG) incorporates the experience of national trachoma programs in their distribution of Zithromax®. It refers to other manuals and guides, specifically the International Coalition for Trachoma Control (ICTC) preferred practice manuals that have been developed since the first edition of the Zithromax® Program Managers' Guide. These manuals and guides (see **Annex 1**) will provide a more comprehensive explanation of the issues and should be used as references.
- ▶ The advice and preferred practices for trachoma elimination are constantly evolving. This ZMG 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, forgoing her opportunity to break the cycle of poverty with a formal education.

1. Introduction



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

1.3: 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 non-governmental partners, academics, and donors.
- ▶ Pfizer announced its donation of Zithromax® for national trachoma programs in 1998, when it established the ITI. Since 2009, ITI has been a program of The Task Force for Global Health, an independent not-for-profit organization. ITI allocates the donated drug according to need as recommended by the Trachoma Expert Committee (TEC).
- ▶ 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.

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 by eye-seeking flies. Children ages 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.

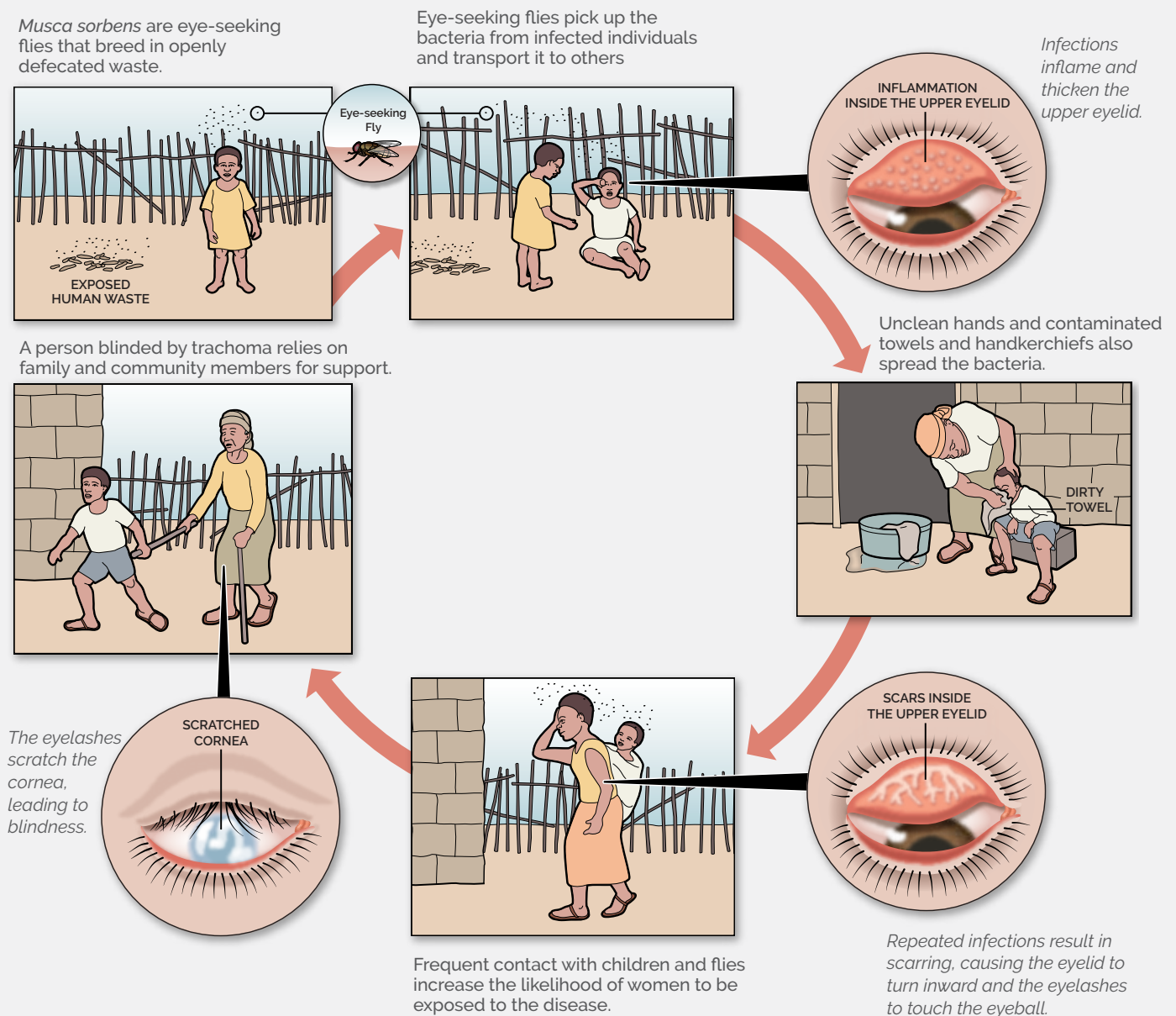


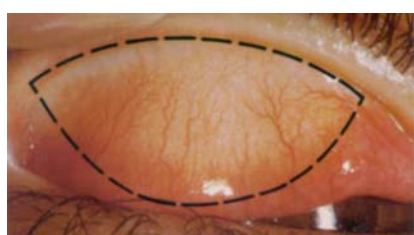
Image Credit: The Carter Center / Graphic by Al Granberg

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 trichomatous 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 5 grades.

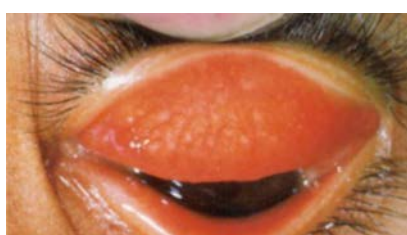
Trachoma Grading Card

- ▶ 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 intumed eyelashed 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 conjunctiva).
- ▶ 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.



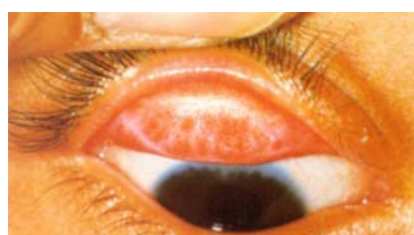
2. Trachomatous Inflammation – Follicular (TF)

- ▶ 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.



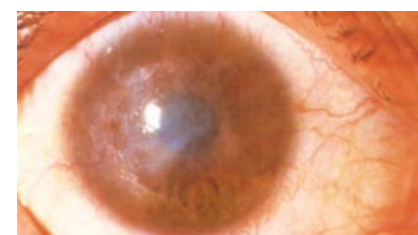
4. Trachomatous Scarring (TS)

- ▶ 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 in-turned 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.





Zithromax® bottles of tablets and Powder for Oral Suspension (POS) at a Mass Drug Administration (MDA) in Zambia. Photo credit: Sumon Ray for the International Trachoma Initiative

2. Zithromax[®] Donation Program

2.1: Qualifying for Zithromax[®]

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

- ❑ There is evidence from a population-based prevalence survey that there is at least one trachoma-endemic district in a country (follicular trachoma $\geq 5\%$ among children ages 1–9 years [TF₁₋₉])
- ❑ The Ministry of Health (MOH) signs a Memorandum of Understanding (MOU) with ITI through The Task Force for Global Health agreeing on how the donated Zithromax[®] should be stored, managed, and distributed
- ❑ There is funding available to support the antibiotic distribution
- ❑ There is a plan for the distribution of Zithromax[®] in the context of the SAFE strategy

The standard operating procedures for submitting the dossier and related templates are available on the WHO's publication resource webpage for trachoma. Please visit this link for more information: <https://bit.ly/2kJabwH>

2.2: Decision-making for Mass Drug Administration (MDA) with Zithromax[®]

The treatment schedule is based on district prevalence of TF₁₋₉ 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 6 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 6 months following the last MDA
- ❑ If TF among children 1-9 years old is 30% to 49.9%, 5 years of annual MDA is recommended, followed by an impact survey at least 6 months following the last MDA
- ❑ If TF among children 1-9 years old is above 50%, 7 years of annual MDA is recommended, followed by an impact survey at least 6 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 **Annex 3**). If the district remains TF₁₋₉ below 5%, then no further MDA in that district is required. If the district returns TF₁₋₉ $\geq 5\%$, then MDA may need to resume. Once all districts in a country achieve TF₁₋₉ $< 5\%$ during surveillance surveys, the country is eligible to submit a dossier for validation of elimination by the WHO.

2.3: Application Process

ITI has an annual application process for all countries applying for Zithromax®. The annual process determines Zithromax® needs for the upcoming program year. ITI provides the TEC with detailed information on the country's trachoma elimination efforts to support the TEC's evidence-based, consistent, and transparent allocations of the drug. The TEC is an independent body of internationally recognized experts that meets twice annually to review country applications for donations of Zithromax®. TEC members provide invaluable advice to ITI on strategic, technical, and operational issues.

The application requests information on program details, including:

- ❑ updates on trachoma prevalence data
- ❑ current population estimate by district
- ❑ treatment distribution data from the previous program year
- ❑ commitment to full implementation of the SAFE strategy
- ❑ funding and implementation partners (government or non-governmental) for each district receiving Zithromax®

The data collected in this process allows ITI and the TEC to:

- ▶ Make evidence-based decisions on Zithromax® allocations.
- ▶ Plan for on-time shipments of Zithromax® to the countries.
- ▶ Forecast future Zithromax® needs for each country.
- ▶ Forecast future Zithromax® needs for the global trachoma elimination efforts.
- ▶ Plan for Zithromax® production with Pfizer for the following five years.

Zithromax® Application Process and Timeline

Month	Activity
January	ITI sends Zithromax® Application to national trachoma program for the upcoming year
March	National trachoma program submits application to ITI
June to November	TEC makes Zithromax® allocation decisions ITI sends MOH notification of TEC decisions and either enters into a new MOU or updates the current 3-year MOU with an addendum
1–2 months prior to MDA	ITI ships Zithromax® 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 Zithromax® application
Prior to shipment	Countries report to ITI on remaining inventory from the prior year

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



Photo credit: International Trachoma Initiative

2. Zithromax® Donation Program



Photo credit: Sumon Ray for the International Trachoma Initiative

District-Level Zithromax® Donation Criteria

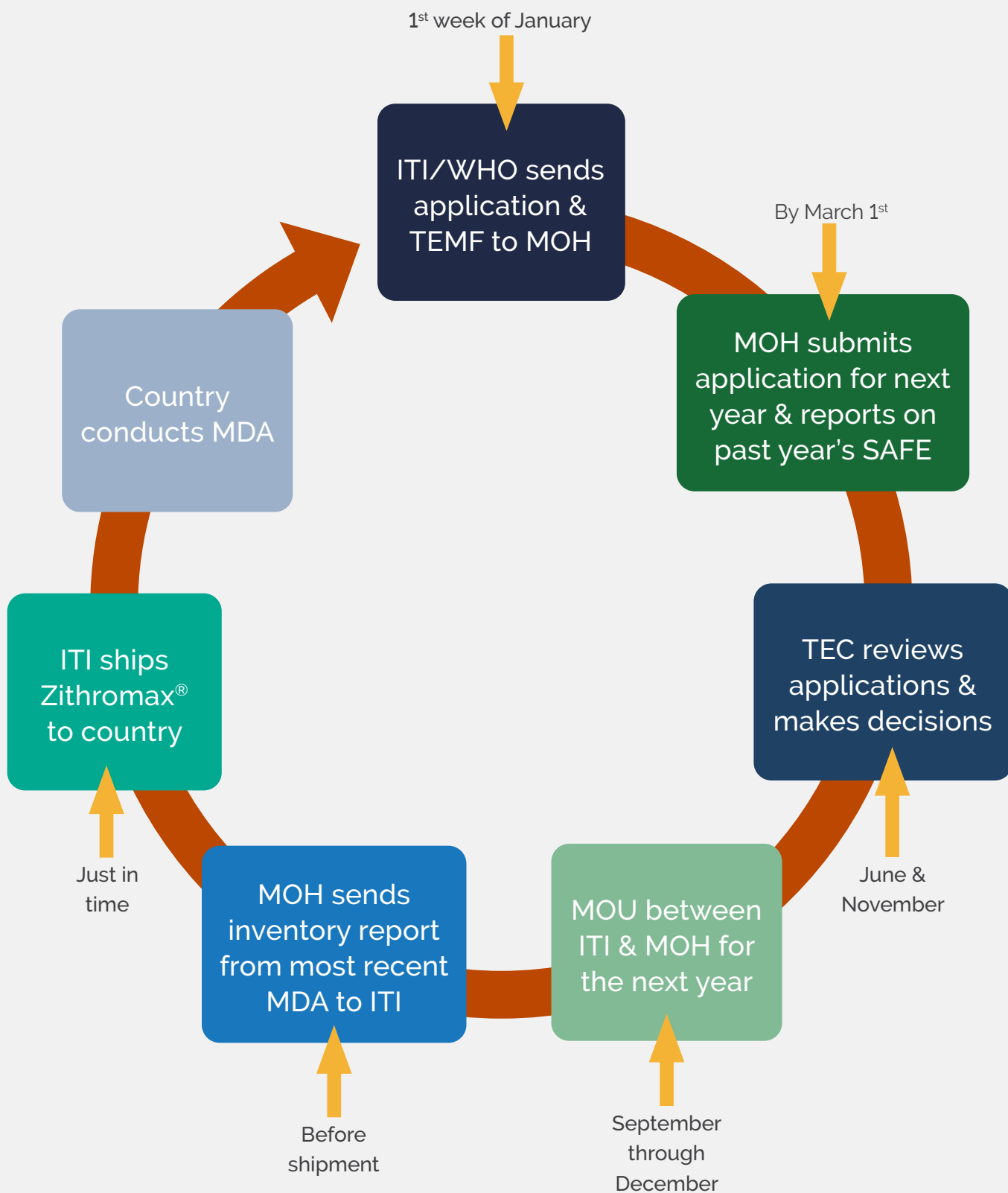
- ▶ TF prevalence among children ages 1 to 9 years \geq 5%.
- ▶ Funding available to support MDA.
- ▶ Commitment to implementing *Facial cleanliness* strategies and *Environmental improvements* in all trachoma-endemic districts, and *Surgeries* as needed.

2.4: Summary

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

- ▶ ITI exists to ensure you receive the right amount of Zithromax® at the time you need it for MDA.
- ▶ The Zithromax® Application document contains two parts:
 - The Alliance for GET2020 Trachoma Elimination Monitoring Form (TEMF) for reporting on the previous year's activities.
 - The Zithromax® Application for the upcoming year.
- ▶ The TEMF is for activities that occurred during the previous year (i.e., the TEMF submitted in 2019 is for activities that occurred in 2018).
- ▶ Zithromax® Applications are for the following year (i.e., an application submitted in 2019 is for the Zithromax® needed in 2020).
- ▶ 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 manager 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 at the TEC meetings.
- ▶ Both the TEMF and the Zithromax® Application are pre-populated by ITI with projected district population figures. The national program should review and make any corrections on the TEMF, which will update the application tab.
- ▶ ITI is always trying to make the Zithromax® 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: Zithromax® Application Timeline



2.6: Application Review

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

- ☐ trachoma prevalence
- ☐ population
- ☐ 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

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

1 Approve Zithromax®
to be allocated for the upcoming year;

2 Approve Zithromax®
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., Zithromax® theft, unauthorized use of Zithromax® 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 TF₁₋₉ < 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 a Zithromax® donation in a future application, if warranted.

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

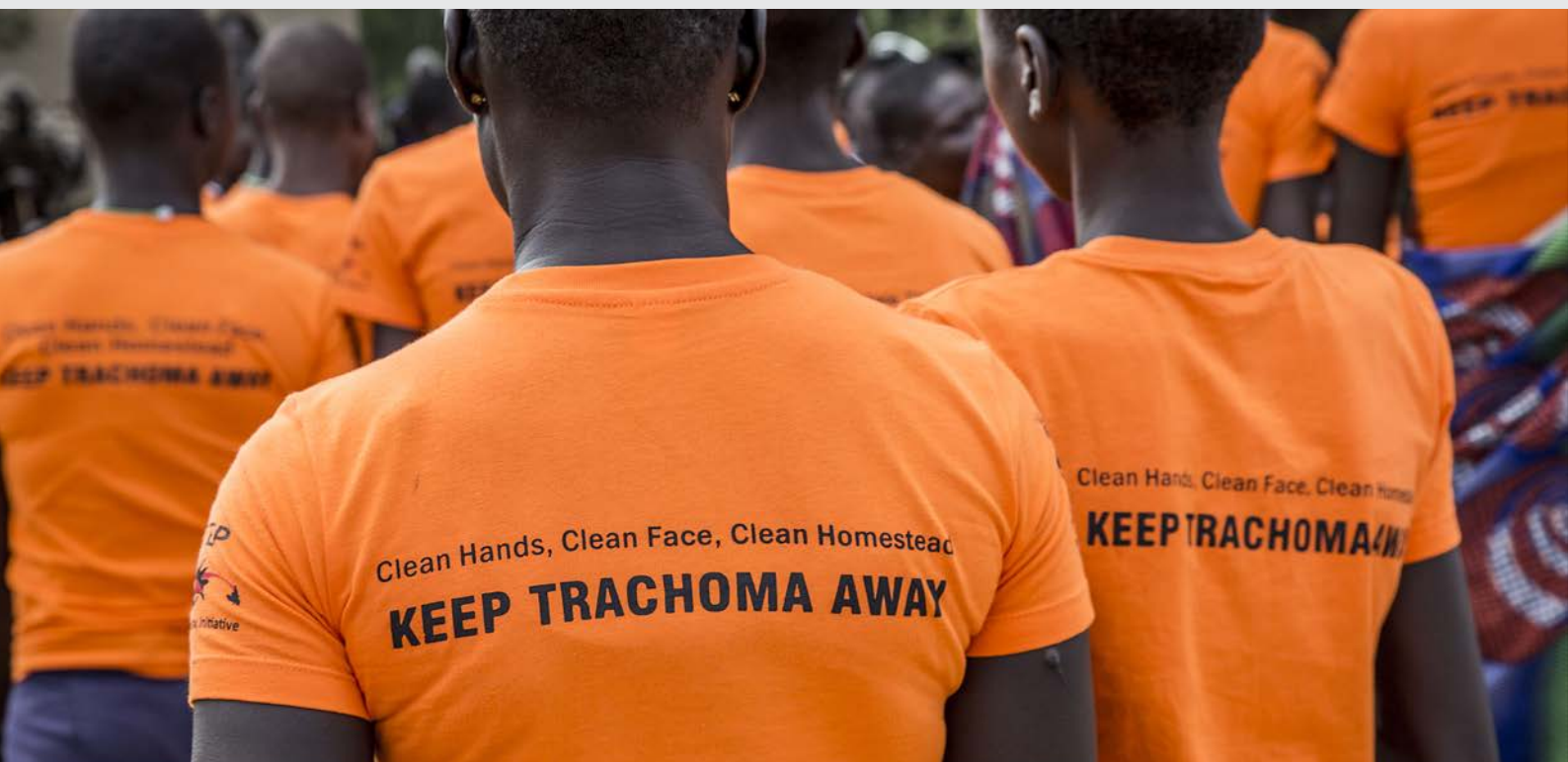


Photo credit: Steven Wade Adams for Pfizer

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 Zithromax®
- ▶ an addendum detailing the Zithromax® allocation decisions for the upcoming year
- ▶ an addendum regarding what is necessary to report to Pfizer regarding Zithromax® product quality concerns, at-risk scenarios, and adverse events, 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.
- ▶ Once the treatment for any year has been allocated, ITI will take the necessary steps to ensure the drug arrives in country prior to the scheduled MDA.
- ▶ Failure to comply with the terms set forth in the MOU may result in suspension of the Zithromax® donation, e.g., administration of Zithromax® for unapproved uses or in areas not approved by the TEC will jeopardize the country's drug donation in the future.



Photo credit: Sumon Ray for the International Trachoma Initiative

2.8: Receiving Zithromax®

- ❑ ITI Supply Chain team will request the country to submit inventory reports immediately following MDA and may request an update no less than 6 weeks prior to receiving the next shipment
- ❑ ITI Supply Chain team will work with the national program to:
 - Re-confirm shipping documentation and importation requirements
 - Determine timing of the shipment
 - If requested or as needed, conduct periodic Supply Chain Assessments in collaboration with the national program to address any systemic issues related to Zithromax® management

For details on supply chain management, please see Part II of this guide entitled “Zithromax® 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 Zithromax® via the TEMF, which is included with the Zithromax® Application and due to ITI in March each year.
 - The TEMF and annual Zithromax® Application have been combined into a single process which includes pre-populated data fields in order 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
 - Each year, national programs must report their post-MDA inventory prior to receiving their next Zithromax® shipment. A standardized reporting form is used to facilitate this and will be provided by the ITI Supply Chain team.



A child waiting to receive his dose of Zithromax® Powder for Oral Suspension (POS) at a Mass Drug Administration (MDA) in Sokoto State, Nigeria. *Photo credit: Sumon Ray for the International Trachoma Initiative*

3. Mass Drug Administration (MDA) Strategy

The key strategy for the distribution of Zithromax® is through MDA. This section will introduce a number of critical aspects for MDA with Zithromax®. Further and more in-depth information is available in the ICTC document “Preferred Practices for Zithromax® MDA”. This is available on the ICTC website: www.trachomacoalition.org.

3.1: Donated Zithromax® for Trachoma

Zithromax® 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 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.
- ▶ There are three dosing cups provided with each bottle of POS.
- ▶ Lot numbers and expiry dates appear on each bottle. The POS is given an expiry of 24 months after manufacture (5 days after reconstitution). Zithromax® expires on the last day of the month indicated on the bottle.



Photo credit: International Trachoma Initiative

Tablets:

- ▶ One bottle contains 500 tablets, 250mg each.
- ▶ The tablets are oval and bright pink.
- ▶ Tablets manufactured prior to August/September 2018 will have “Pfizer” stamped on one side and the number “306” on the other. Tablets manufactured after this date will have “Pfizer” stamped on one side and “ZTM 250” on the other.
- ▶ Lot numbers and expiry dates appear on each bottle. Tablets are given an expiry of 48 months after manufacture (36 months after opening). Zithromax® expires on the last day of the month indicated on the bottle.



Photo credit: Billy Weeks for the 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 label states “Donation for treatment of trachoma only”. No other packaging is used for donated Zithromax®.



Photo credit: Steven Wade Adams for Pfizer

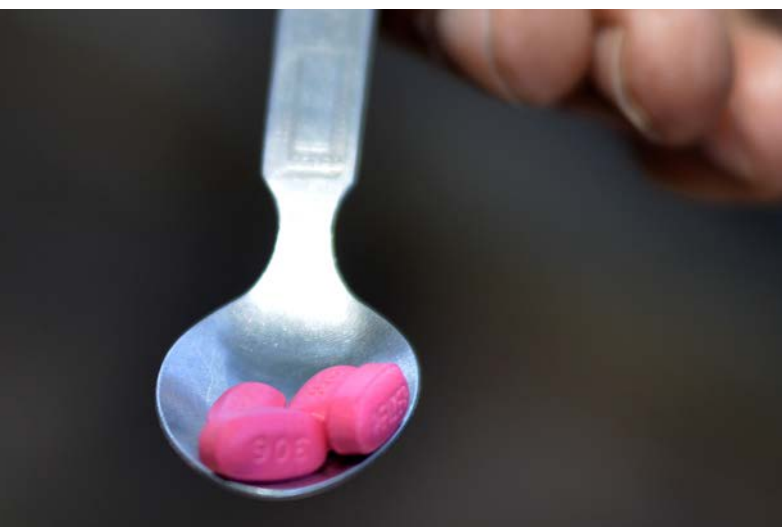


Photo credit: Billy Weeks for the International Trachoma Initiative

3.2: Population Eligible for Zithromax®

All individuals in trachoma-endemic communities older than six months are offered an annual single oral dose of Zithromax®. The dose 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 Zithromax® reconstituted POS, at a dose determined by height (see figure on page 23).
- ▶ 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 Zithromax® 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.

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 Zithromax® tablets. The dose will be either 3 or 4 tablets, determined by height (see figure on page 23).
- ▶ Individuals aged 15 years and older should be offered a full adult dose of 4 tablets of Zithromax®, 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 Zithromax®. If they decline, they should be offered tetracycline eye ointment (TEO).

3. Mass Drug Administration (MDA) Strategy



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 Zithromax® 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 aged ≥ 7 years and < 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 Zithromax® or TEO) divided by the total number of residents of the endemic district.
- The target population coverage is 100% of the eligible population.
- Note that the program should plan against the actual population residing in the district.
- 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, indigenous populations, and migrant workers.
- If the national program is interested in treating internally-displaced persons and/or refugees with donated Zithromax®, please see **Annex 4** for a flow chart for decision-making.

3. Mass Drug Administration (MDA) Strategy



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

3.5: Treating Children

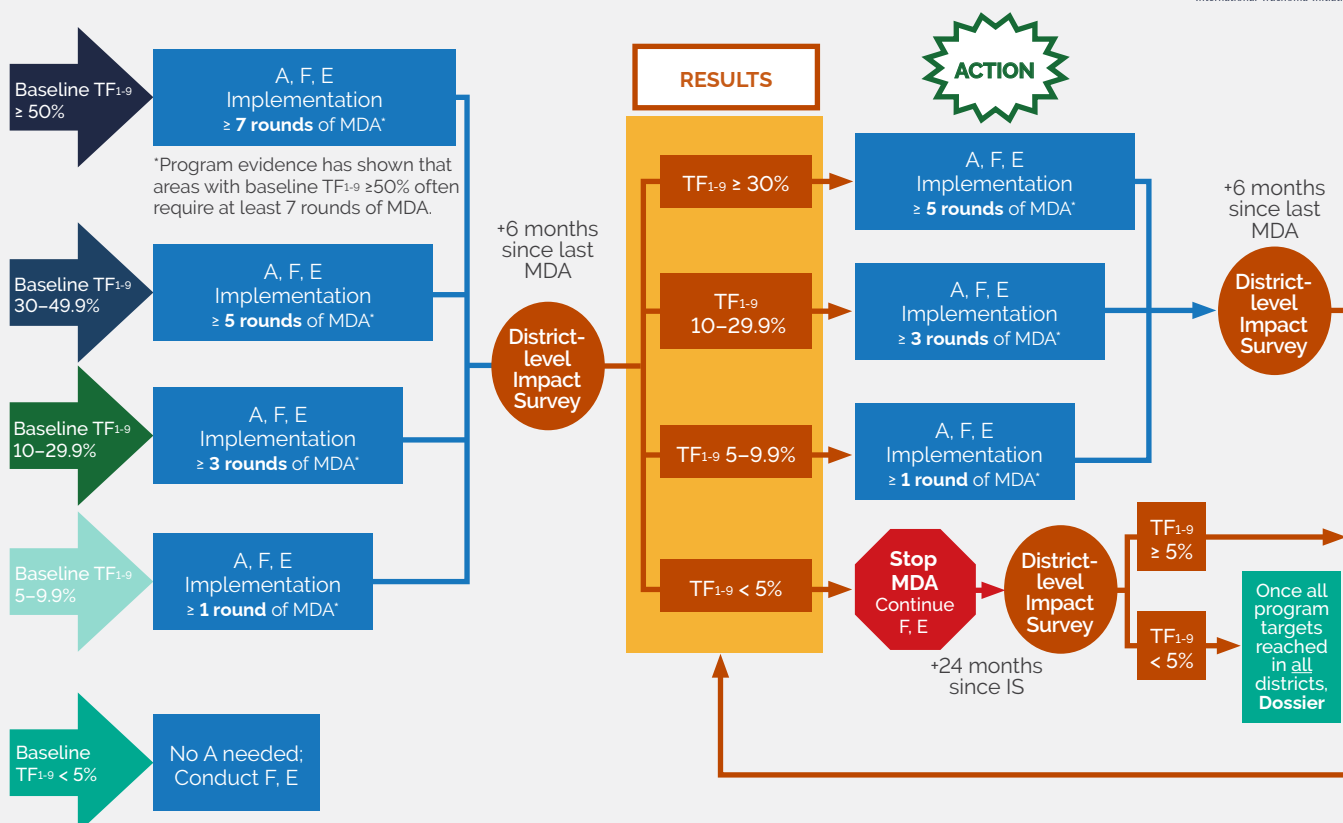
- ▶ The treatment of children with Zithromax® requires caution to avoid choking and the following points need to be incorporated into the training of distributors and supervisors.
- ▶ No child should ever be forced to take Zithromax® (neither tablets nor POS).
- ▶ Distributors must directly observe treatment to ensure that each individual takes the correct dose for him or her. Under no circumstances should individuals be allowed to administer Zithromax® 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 Zithromax® 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 Zithromax® to a child, NEVER hold the child's nose closed, shake the child, or push 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. MDA with Zithromax® is a public health program and 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: Distribution Duration and Frequency

The duration of treatment is based on the prevalence of clinical signs of trachoma among children ages 1–9 years as determined by 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 6 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 6 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 6 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 6 months following the last MDA

Diagram on Decision Making for the Antibiotic Treatment of Trachoma
(See Annex 3 for a larger version of this graphic.)



3.7: Training Distributors

Different countries use different types of health workers to distribute Zithromax®. Many use community volunteers while other countries utilize staff from the MOH system. Training of 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, Zithromax® 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 in lieu 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 Zithromax® 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 27 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 Zithromax® 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.

The following tips are useful:

- ❑ 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

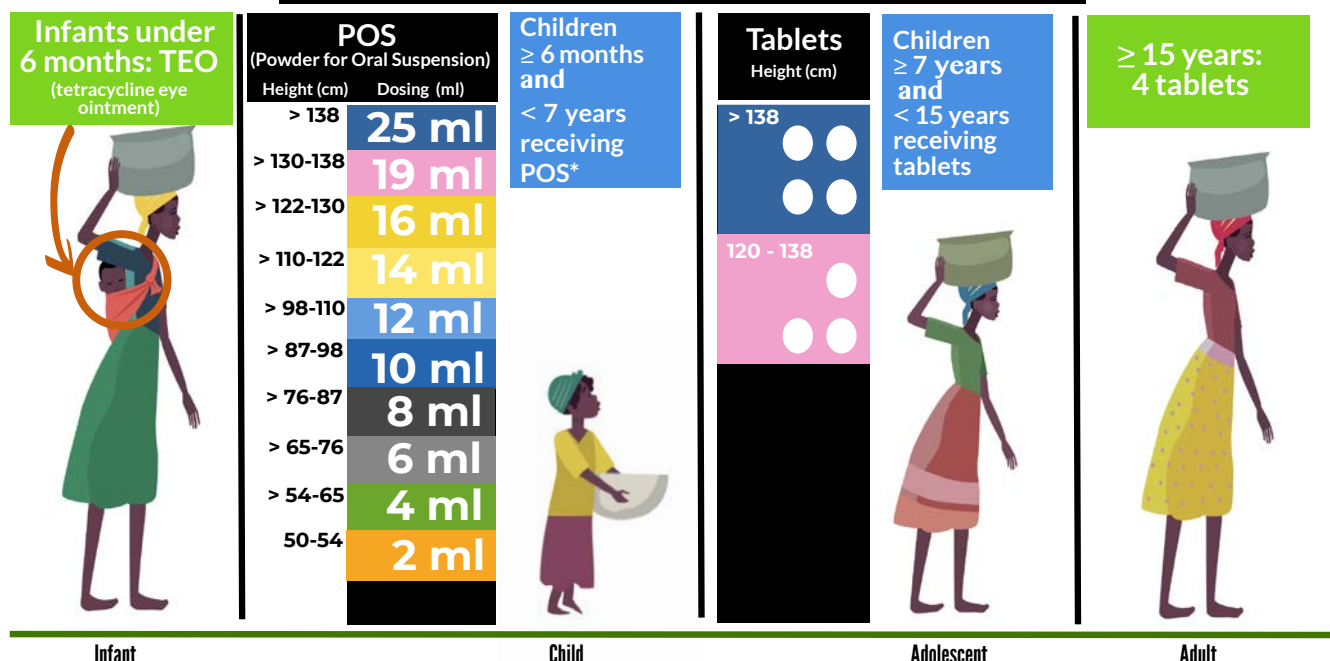
If using a paper tape rather than a wooden stick, the tape should be fixed to a wall and the person can then stand next to the wall. Do not attempt to use a loose tape on its own as a measuring device.

3. Mass Drug Administration (MDA) Strategy

Version 2: Updated August 2020

Height- and Age-Based Dosing for Zithromax® POS and Tablets

July 2018



***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.

Version 2: Updated August 2020



Zithromax® Dosing Guidelines

July 2018

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)	Powder for Oral Suspension (POS) dosed according to height
Individuals under 120 cm (regardless of age)	
Individuals with difficulties swallowing tablets or uncomfortable taking tablets	
Individuals taller than 120 cm <u>and</u> 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 ZITHROMAX®
No child should ever be forced to take Zithromax®.
Distribution sites can be intimidating for children. If the child is uncooperative or anxious, the parent or guardian is the correct person to administer Zithromax® 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 Zithromax® 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.

(See Annex 5 for a larger versions of these graphics.)



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 Zithromax® 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 Zithromax® 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.

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.



Photo credit: Mark Tuschman for the International Trachoma Initiative

3.8: Community Awareness

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

- ❑ Trachoma prevention and blindness from trachoma
- ❑ The reason for treatment with Zithromax[®]
- ❑ Zithromax[®] is a very safe drug to take
- ❑ Minor side effects of taking Zithromax[®] are nausea and diarrhea, which can be avoided by not taking the drug on an empty stomach
- ❑ The precise location and dates of treatment
- ❑ Zithromax[®] 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

3. Mass Drug Administration (MDA) Strategy



A mother administering Zithromax® 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

3.9: Safety of Zithromax®

- ▶ Zithromax® 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 stomach upset.
- ▶ Individuals who experience mild side effects should be reassured that in spite of their symptoms they should take Zithromax® 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
 - ❑ 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.
- ▶ **Serious Adverse Event (SAE):** leads to death, hospitalization, disability, or harm to a fetus.

Please see **Annex 6** for additional information on safety reporting requirements.



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

3.10: Reporting Process for Adverse Events (AEs)

- ❑ The MOH shall report all potential AEs, via the Pfizer-directed reporting mechanism **within twenty-four hours of awareness** (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 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
- ❑ There should be a designated person 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 “**A Handbook for Adverse Events Following MDA and Serious Adverse Events**” on the RTI ENVISION website for more in-depth information on SAEs for Neglected Tropical Diseases (NTDs).



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

3.11: 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 whole 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, please consider the following:

- ▶ Be proactive in implementing ongoing activities and in 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 deal with rumors, as doing so will benefit the MDA campaign now and in the future.

Please remember:

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

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.



Photo credit: Sumon Ray for the International Trachoma Initiative

3.12: Supportive Supervision

Supervision of the Zithromax® distributors is an essential aspect of the program to ensure that: optimal coverage is achieved, Zithromax® 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 him/herself 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 have strong communications skills, be a team builder, and serve as a mentor.
- ▶ The supervisor's task is to assess the distribution exercise, the work of the community drug distributors (CDDs), and gather information on any cases of SAEs after taking the drug.
- ▶ The supervisor's goal is a successful MDA, which is defined as an MDA that has been done safely, efficiently and has achieved the optimal coverage of 80% or more.

For further information on how to train supervisors in supportive supervision, please refer to the manual **"Supportive Supervision for Mass Drug Administration with Zithromax"** found on the ICTC website.

Zithromax® Supply Chain Management Guide



The production of Zithromax® involves three continents and a complex, high-tech supply chain ending with the last mile where sufficient drug for a community is collected by the Community Drug Distributors (CDDs) and transported using methods that are suitable for the local context. Alametü Metalign and Terengku Mulat are loading a donkey with the Zithromax® allocations, dosing poles, log books and other supplies required for the Mass Drug Administration (MDA) in their community in Adet town, Amhara Region. *Photo Credit: Brent Stirton/ Getty Images for the International Trachoma Initiative*

Table of Contents

1. Shipment Planning and Coordination	3
1.1: Introduction to Zithromax® for the Supply Chain Manager	3
1.2: Preparing for Shipment	6
1.2.1: In-Country Inventory	6
1.2.2: Approved Districts and Quantities	6
1.2.3: Shipment Calculation	6
1.2.4: Shipment Calculation Tool	7
1.2.5: Contact List	7
1.2.6: Certificate of Donation, Pro Forma Invoice, and Commercial Invoice	8
1.2.7: "Green Light" for Zithromax® Shipment	9
1.2.8: Final Shipping Documents from ITI	9
1.2.9: Final Arrangements for the In-Bound Shipment	10
1.2.10: The Zithromax® Shipment Tracker	10
1.2.11: Customs Clearance	11
1.2.12: Confirmation of Receipt	11
2. In-Country Supply Chain Management of Zithromax®	13
2.1: Drug Movement in Preparation for MDA Schedule	13
2.1.1: Allocation Schedule	16
2.1.2: Distribution Plan	17
2.1.3: Transportation Plan	18
2.1.4: In-Country Shipment Plan	18
2.1.5: Zithromax® Product Specifications	19
2.2: Managing the Zithromax® Inventory	20
2.2.1: Physical Inventory of Zithromax®	22
2.2.2: Issuing Zithromax® from Storage	23
2.2.3: Record Keeping	24
2.2.4: Managing Close-Dated Drugs	26
2.2.5: Managing Damaged or Expired Drugs	27
2.2.6: Zithromax® Disposal Methods	27
2.2.7: Managing Empty Bottles	29
3. Supply Chain Assessments	31
Conclusion	33



Zithromax® tablets and Powder for Oral Suspension (POS) at a Mass Drug Administration (MDA) training in Zambia. This MDA training took place in the Lubushi Health Center in the Kasama district of Zambia.
Photo credit: Sumon Ray for the International Trachoma Initiative

1. Shipment Planning and Coordination

1.1: Introduction to Zithromax® for the Supply Chain Manager

- ▶ The target audience for this section of the Zithromax® Management Guide (ZMG) is primarily any person or organization that is responsible for the supply chain management of Zithromax® for trachoma control and elimination, including shipment planning, customs clearance, transportation, warehousing, inventory management, distribution and reverse logistics.
- ▶ Zithromax® for trachoma is an antibiotic (azithromycin) 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 Mass Drug Administration (MDA) to the national trachoma or Neglected Tropical Diseases (NTDs) program.
- ▶ Zithromax® is presented in two forms: Powder for Oral Suspension (POS) and tablets:
 - Powder for Oral Suspension (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.
 - There are three dosing cups provided with each bottle of POS.
 - Lot numbers and expiry dates appear on each bottle. POS has a shelf life of 24 months after manufacture (5 days after reconstitution).
 - Zithromax® 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.
 - Tablets manufactured prior to September 2018 will have "Pfizer" imprinted on one side and the number "306" on the other. Tablets manufactured after September 2018 will have "Pfizer" imprinted on one side and "ZTM 250" on the other.
 - Lot numbers and expiry dates appear on each bottle. Tablets have a shelf life of 48 months after manufacture (36 months after opening).
 - Zithromax® expires on the last day of the month indicated on the bottle.



Photo credit: International Trachoma Initiative

1. Shipment Planning and Coordination

- ▶ For both POS and tablets, the bottle labels are a unique and distinctive purple, with writing in English and in French. The label states "Donation for treatment of trachoma only". No other packaging is used for donated Zithromax®.
- ▶ This section will help supply chain managers ensure that Zithromax® 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 7** 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 Zithromax® supply chain management.

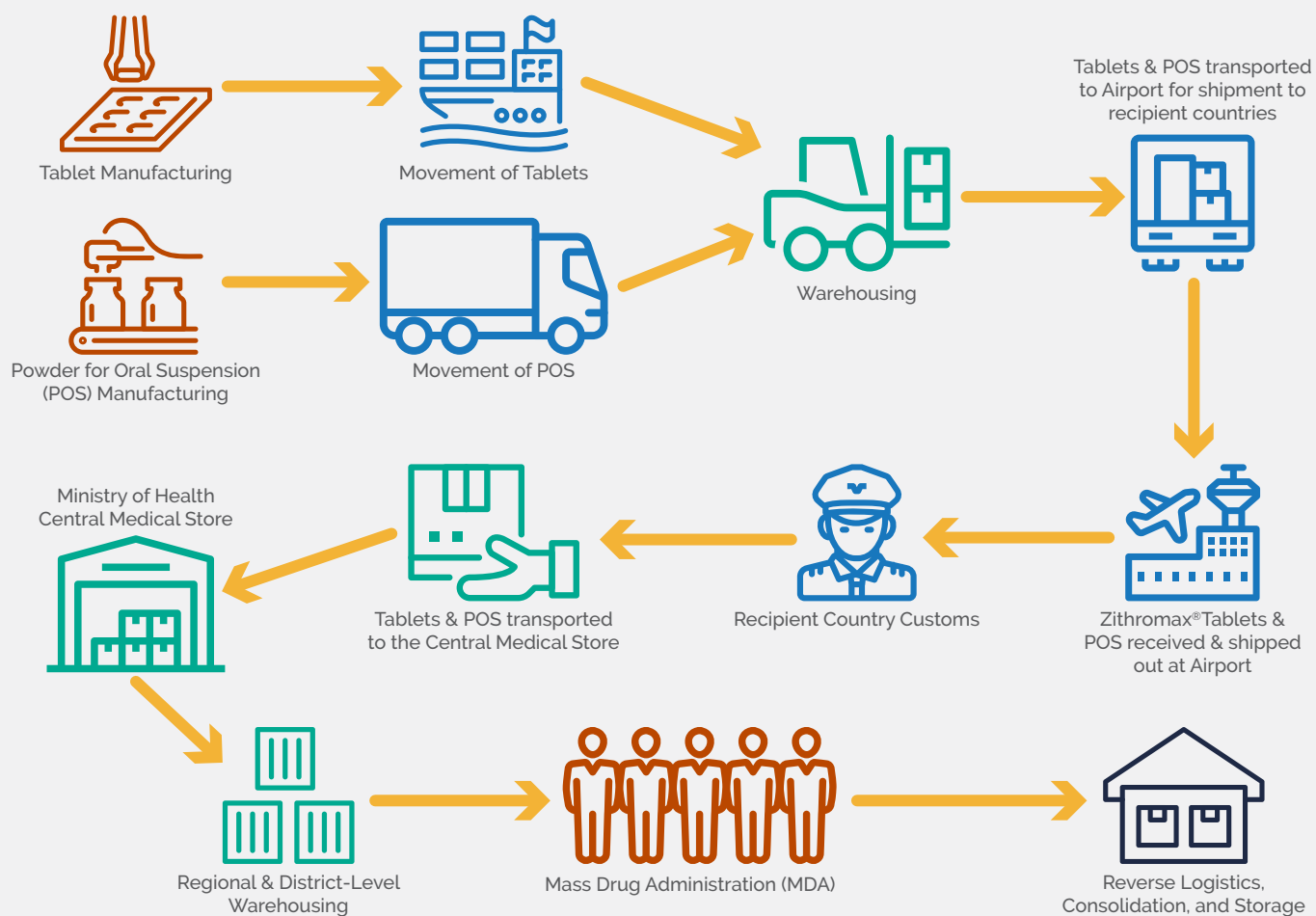
*Pfizer donates Zithromax®
for the exclusive purpose
of trachoma control for
MDA in approved districts,
research, or surgery.
Zithromax® must not be
used for any other purpose.*



Photo credit: DSV Global Transport and Logistics

1. Shipment Planning and Coordination

Zithromax® Supply Chain Overview



Color Key:

Product and Product Application
Transportation
Storage
Debrief

1.2: Preparing for Shipment

ITI Supply Chain Team's goal is to deliver Zithromax® 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 the Trachoma Expert Committee (TEC), supply chain managers are requested to follow the steps outlined below to ensure that the correct amount of Zithromax® is shipped by ITI in a timely manner.

Prior to Zithromax® arriving in-country, there are a number of steps that a country needs to take:

1.2.1: In-Country Inventory

- ▶ ITI will send an inventory form and instructions to the program on an annual basis during the month of MDA.
- ▶ Physical inventory should start immediately after MDA. The inventory report should be submitted to ITI in the requested format no later than 10 days after MDA.

1.2.2: Approved Districts and Quantities

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

1.2.3: Shipment Calculation

ITI calculates the amount of Zithromax® 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 Zithromax® tablets or POS (eligible population).
 - 80% of the eligible population is estimated to be 7 years or older and thus will receive Zithromax® 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 Zithromax® POS.
- ▶ 2% of the population is estimated to be 0–6 months of age and therefore not eligible for treatment with Zithromax®. These children should be treated with tetracycline eye ointment (TEO). ITI does not provide TEO to countries.

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

1. Shipment Planning and Coordination



Once the Zithromax® tablets and POS are manufactured, they are sent to Pfizer's European Logistics Center (ELC) in Belgium. Based on drug distribution schedules in the recipient countries, ITI places an order with the ELC to ensure that the right amount of drug is sent to the communities in need at the right time. This image shows a 2017 shipment to Ethiopia being staged at the loading dock at the ELC. At 589,152 bottles and 384 pallets, it was the highest volume of a single Zithromax® shipment to any country to-date. Each pallet of Zithromax® tablets has approximately 215,000 doses and each pallet of POS has approximately 6,144 doses. *Photo credit: DSV Global Transport and Logistics*

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 8**.

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.

In order for the Shipment Calculation Tool to be 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:
 - National Program Coordinator (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 9**) needs to be up-to-date to avoid any delays in shipping.

1. Shipment Planning and Coordination



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 10) will contain the following information:

1. Quantity of Zithromax® to be donated to the country program.
2. Statement that Zithromax® 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 Zithromax® donation is only for use in trachoma programs.

Generally, a pro forma invoice (see Annex 11) will contain the following information:

1. Brief product description.
2. Quantity of Zithromax® 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. Batch number, manufacturing date, and expiration date.
3. Invoice number.

1.2.7: "Green Light" for Zithromax® Shipment

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

Zithromax® Shipment Green Light Checklist		Yes/ No
Communication	Are the Customs agents aware of the shipment and the quantity of the shipment?	
Customs Duty Waiver	Has the Customs duty waiver been prepared?	
Customs Clearance & Handling Costs	Are the funds ready to pay Customs clearance and handling costs for the inbound shipment?	
Warehouse Space	Does the Central Medical Store have space to receive the shipment?	
Distribution	Is the country prepared to distribute the Zithromax®?	

Once the answer to all questions is "Yes", the NPC will send the green light notification to ITI that the Zithromax® 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
- ☐ Airway Waybill or Bill of Lading (see **Annex 12**)

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 also sent via courier if they are required for customs clearance.



A Zithromax® shipment to Nigeria is being loaded on a plane in Luxembourg airport.
Photo credit: DSV Global Transport and Logistics

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

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 Zithromax® Shipment Tracker

ITI launched The Zithromax® Shipment Tracker in 2017. The Tracker is a web-based tool that provides users with real-time access to information about recent and upcoming shipments of Zithromax® to recipient countries in an easy-to-follow electronic format. The Tracker provides information about the quantities of drugs requested via the Zithromax® Application, current decisions made by the TEC, quantities shipped year-to-date, quantities remaining to be shipped, expected arrival date, and mode of transport. Program managers and supply chain managers can easily follow the progress of the approved drug for their country.

To subscribe and begin receiving automated email updates for your country, please visit the following link: <https://www.trachomadata.org/supply-chain/subscription>

Zithromax® Shipment Tracker

Zithromax® Shipment Tracker by Country

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

Zithromax® Shipment Tracker - Country

Powered by GET2020 Database

2019

2019 TEC Decision - Current	
Approved MDA	1,769,983
Approved - Surgery/Research	No Approved Surgeries/Research
Contingent Approvals	
Reserve 1: Funding and/or partner not confirmed	No Reserve 1
Reserve 2: Awaiting impact survey results	731,993
Reserve Special: Special Concerns	170,315
Does Not Meet Criteria	900,490

2019 Shipment Summary

2018 Carry Over	260,688
2019 Total Planned Shipment	1,396,816
Shipped Year to Date	1,551,166
Remaining to be Shipped	108,336

Shipment Information

Shipment	Planned Shipment Month	Planned MDA Month	POS (Bottles)	TABS (Bottles)	# of Treatments	Shipment Date	Arrival Date	Mode
Shipment #1	January	January	62,223	312	260,688	2019-01-18	2019-01-20	Air
Shipment #2	April	June	128,416	4,680	1,290,480	2019-04-05	2019-04-07	Air
Shipment #3	April	June	4,176	552	108,336			Air

Shipment Tracking

Legend: ■ Completed ■ Cancelled ■ Outstanding Issues ■ Not Completed

Shipment	MOU Signed	Inventory Report Submitted	Green Light Issued	Order Submitted	Order Packed	Order Shipped	Shipment Arrived	Confirmation of Receipt
Shipment #1	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed
Shipment #2	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed
Shipment #3	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed

1. Shipment Planning and Coordination



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 Zithromax® to a designated port of entry. The country is responsible for clearing the product and transporting it to Central Medical Stores. Once the Zithromax® 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 7**.
- ▶ Physical damage.
- ▶ Loss of the drug (e.g., theft, expiry).

1.2.12: Confirmation of Receipt

When the shipment has been cleared from customs, Central Medical Stores should provide confirmation of the total physical quantity of bottles of Zithromax® (both tablets and POS) received in good condition. A confirmation of receipt form (see **Annex 13**) should be sent to ITI within 7 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 the section on Physical Inventory). Any damage or loss that occurred in the shipment process should also be noted, with the exact amount of bottles lost or damaged, on the confirmation of receipt form.



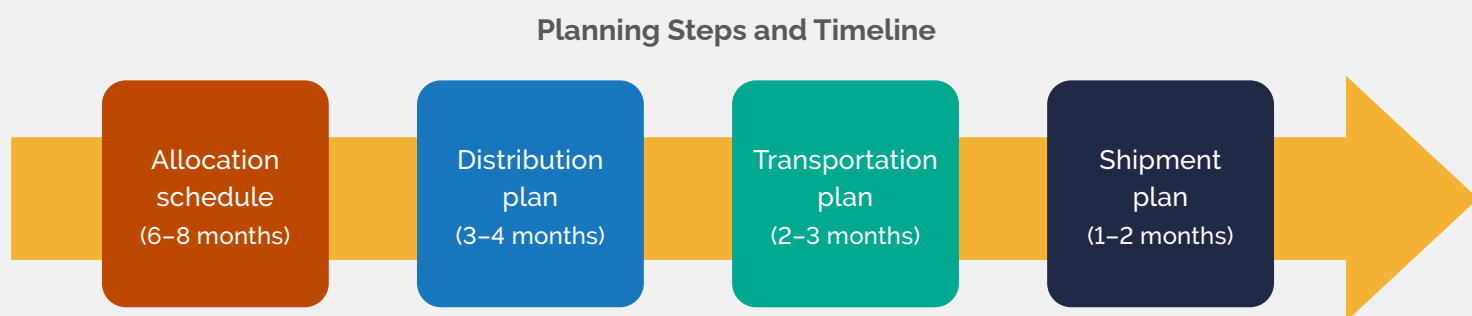
Abebaye Assefa (left) and Etsegenet Kindie (right) are preparing the drugs allocated for Yilemana Denesa woreda's Mass Drug Administration (MDA) with Zithromax®. Etsegenet, the health center coordinator, will transport the allocations to the health center where they will be subdivided for the individual distribution teams. The last mile of the supply chain is reached by foot, horse carts, donkey carts, and bicycles. Yilemana Denesa Woreda, Amhara region. *Photo Credit: Brent Stirton/Getty Images for the International Trachoma Initiative*

2. In-Country Supply Chain Management of Zithromax®

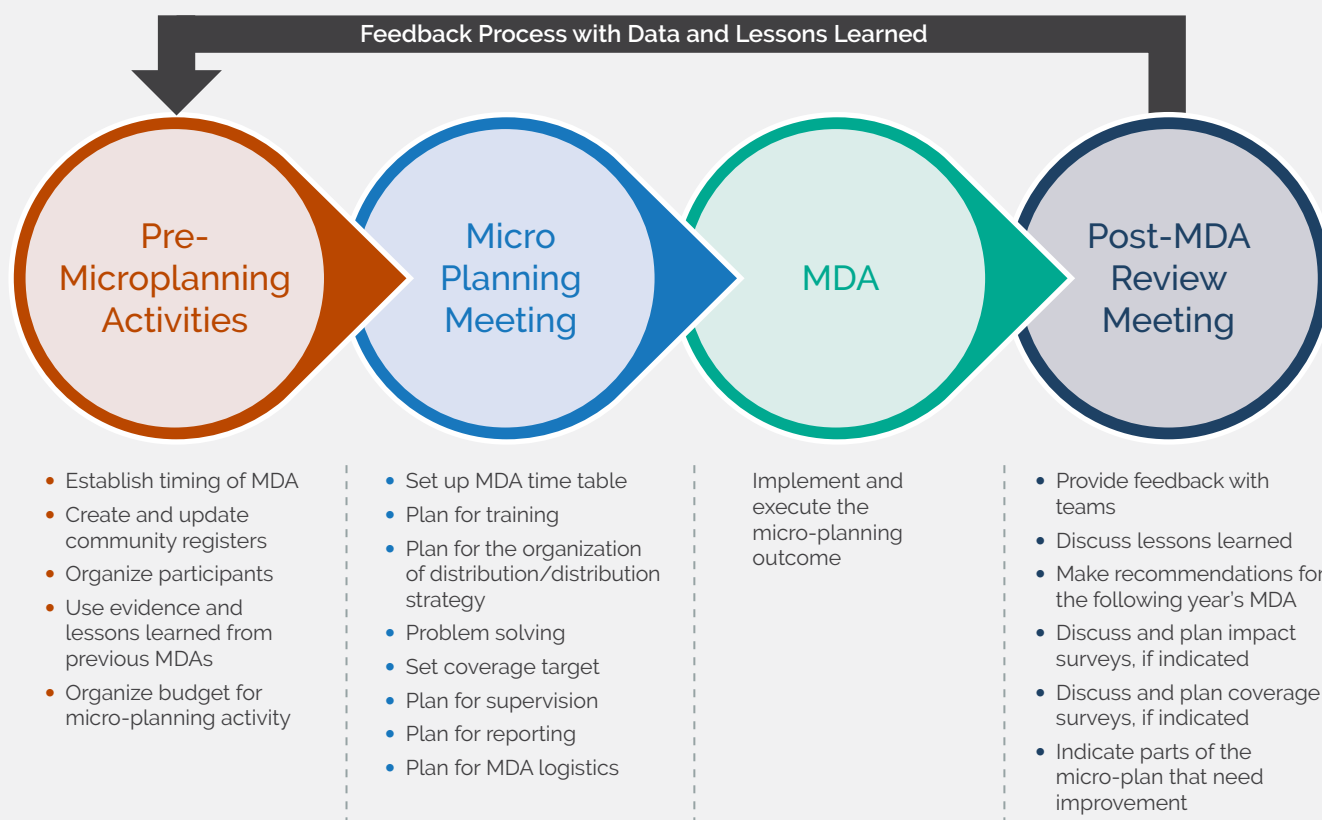
2.1: Drug Movement in Preparation for MDA Schedule

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



MDA Logistics Planning in Two Steps

1. Draw the MDA distribution network:



2. For each distribution point, define and budget:

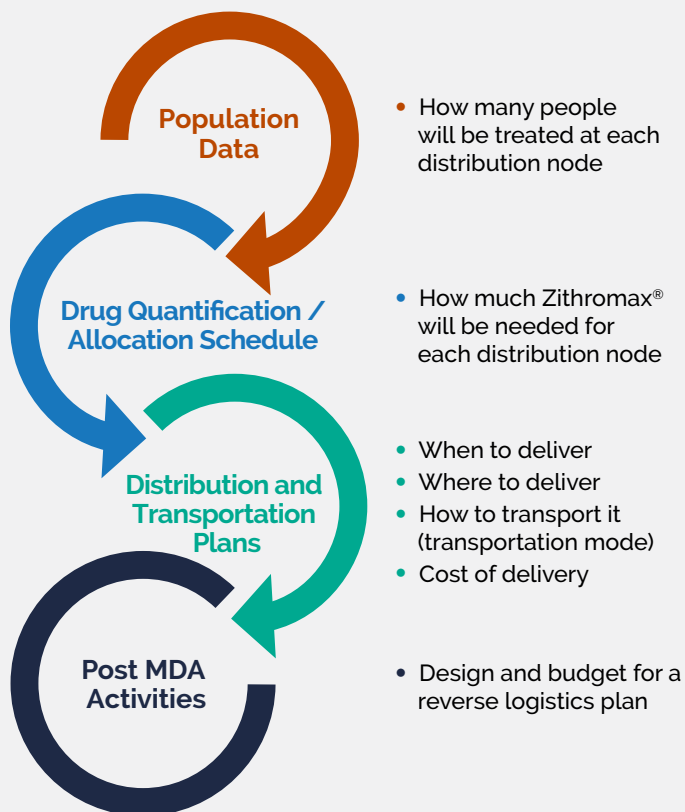




Photo credit: Brent Stirton/Getty Images for the International Trachoma Initiative

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

2.1.1: Allocation Schedule

An Allocation Schedule (see **Annex 14** for template) gives an estimate of the quantity of Zithromax® 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 Zithromax® that should be sent to regional/district storage facilities based on the TEC-approved district allocations.
- ▶ Zithromax® must only be allocated to districts that have been approved by the TEC. Allocating drug to non-approved districts is considered a violation of the MOU and will jeopardize a country's potential to receive Zithromax® 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 Zithromax® 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.

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

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

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

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

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

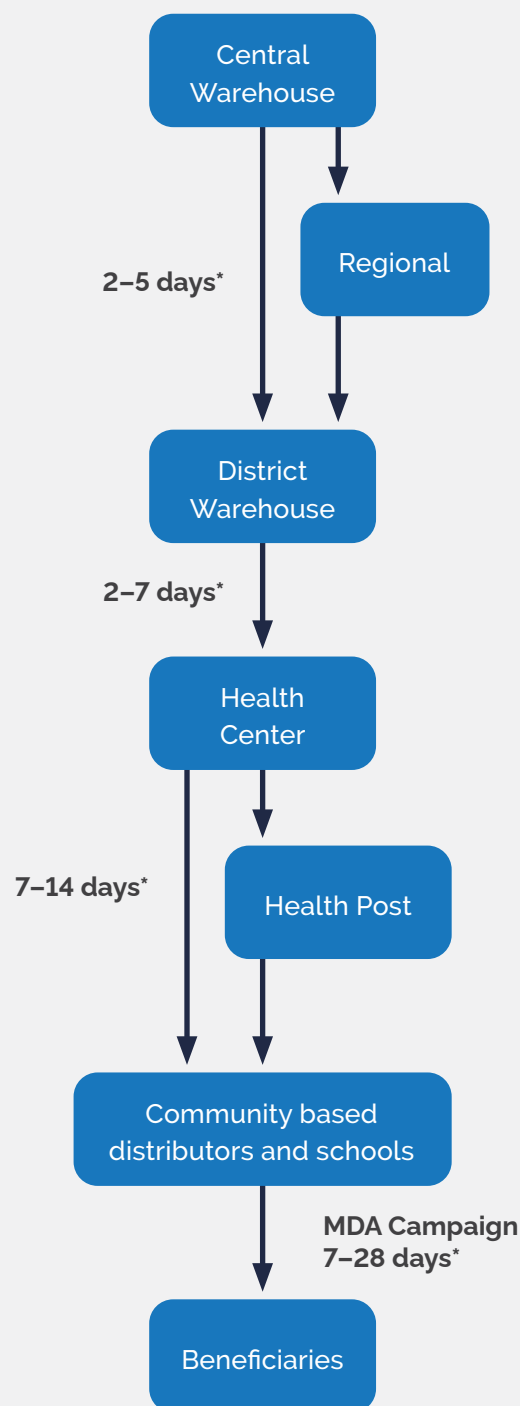
2.1.2: Distribution Plan

Once the allocation schedule has been created, the supply chain manager must develop a distribution plan. The distribution plan outlines the physical flow of Zithromax® from Central Medical Stores 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 Zithromax® must ensure sufficient storage capacity for the product by the earliest delivery date.
- ▶ It is advisable that all districts receive the Zithromax® supply in the full quantity required for the MDA at least two weeks before the distribution begins.

Zithromax® can only be distributed in specific districts approved by the TEC.

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 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 Zithromax® before the distribution begins.
- ▶ If a district requires less than a full truckload of Zithromax®, 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 Zithromax® shipments with any other medical supplies shipments including other NTD drugs going to the same destination from the central warehouse.

- ▶ Ensure that drugs intended for different districts are properly labeled and, if possible, separated from each other to avoid mixing of allocated quantities and batch 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. In case of any inconvenience with the shipment date, always communicate with the receiving facility before sending the shipment.

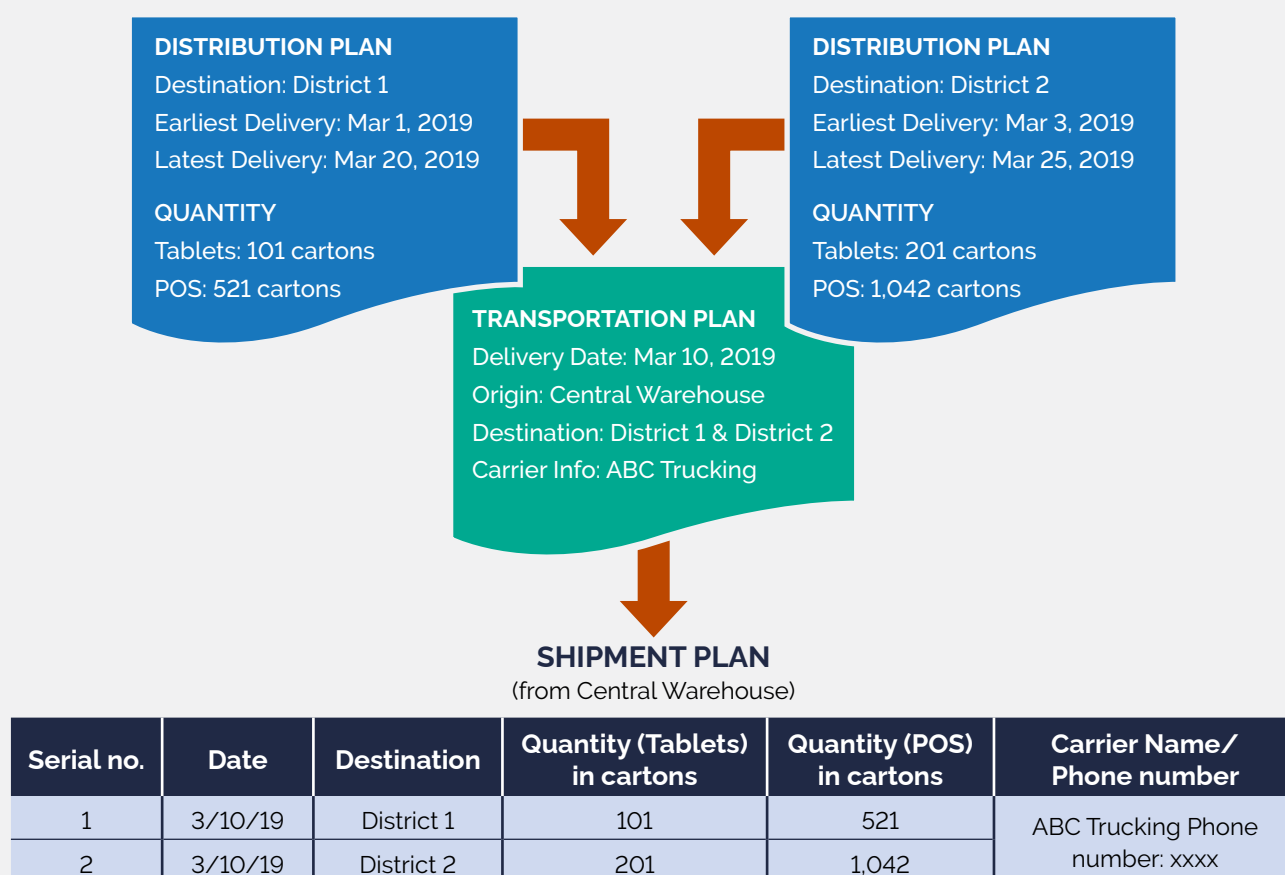




Photo credit: Paul Emerson for the International Trachoma Initiative

2.1.5: Zithromax® Product Specifications

Suppose Country X uses an average of 4 treatments/bottle of POS and 166 treatments/bottle of tablets, Zithromax® product and packaging specifications would be as follows:

Zithromax® for Trachoma	Pediatric Oral Suspension	Tablets (Bottles of 500)
Average Treatments/Bottle	4	166
Bottles per Carton	48	24
Dosing Cups per Carton	144	N/A
Cartons per Pallet	32	54
Average Treatments/Pallet	6,144	215,136
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 months	48 months
Shelf Life (Opened)	5 days after reconstitution	36 months

Zithromax® expires on the last day of the month indicated on the bottle.

Zithromax® cannot be distributed after its expiration date!



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

2.2: Managing the Zithromax® Inventory

Receiving and storing Zithromax®

- ▶ Ensure that there is sufficient storage space.
- ▶ Prepare and clean the areas used for receiving and storing the cartons.
- ▶ Cartons received should be physically counted and inspected (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 *Record Keeping*).
- ▶ A transfer form (see **Annex 17** for example) must be completed each time Zithromax® 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 batch 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 Zithromax® tablets and POS in separate stacks.
- ▶ Do not combine bottles of Zithromax® that have different batch numbers in the same carton.
- ▶ Do not combine tablets from open bottles of Zithromax® to make a full bottle — you may inadvertently mix batches of tablets with differing 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 Zithromax® in a facility where the temperature is below 30° Celsius.
- ▶ Zithromax® should not be exposed to direct sunlight.
- ▶ Segregate damaged or expired drugs from usable Zithromax®. 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 Zithromax® in a manner to facilitate First Expiry – First Out (FEFO). Zithromax® with the earliest expiry date should be used first.



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

Improving Security of the Zithromax®

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 stakeholders (traditional leaders, medical store authorities, patent medicine vendors union, pharmaceutical societies, etc.) to implement measures to prevent the theft of Zithromax®, or to track diverted Zithromax® in the event of theft.

2.2.1: Physical Inventory of Zithromax®

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 Zithromax®. A sample inventory form is included as **Annex 15**.

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 Zithromax® tablets and POS separately
- ❑ Arrange the Zithromax® tablets and POS by expiry date
- ❑ 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 batch 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 15**)
- ❑ Count the number of bottles per expiry date group
- ❑ Any reconstituted POS bottles should not be included in the inventory but disposed of within 5 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**

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 Zithromax® from Storage

When issuing drugs from storage:

- ▶ Follow the FEFO policy at all levels (i.e., central, district, community levels).
- ▶ Issue Zithromax® 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 Record Keeping section).

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

Task	Distribute Zithromax® according to the FEFO distribution principle.
Completed by	Store Pharmacist-in-charge, Pharmacy Technician or Medical Store Managers.
Purpose	To ensure that Zithromax® is distributed before it expires.
When to Perform	Whenever Zithromax® 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 Zithromax® so that stocks first to expire are stacked in front or on top of stocks that will expire later.
3	Issue Zithromax® stocks from the front to back or from the top to bottom so that Zithromax® stock that will expire sooner will be issued first.
<i>Do not follow First-in, First-out (FIFO)</i>	



Photo credit: Brent Stirton for the International Trachoma Initiative



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

2.2.3: Record Keeping

Record keeping is the most essential part of inventory management. Zithromax® inventory is accounted for on two important forms (see **Annexes 16 and 17** for examples):

- ▶ Stock cards.
- ▶ Transfer forms.

Use these two forms to keep track of Zithromax®. 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 Zithromax® is transported from one location to another.

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

Stock Card (see Annex 16 for example):

- ▶ Stock cards are used to record receipts, issues, and adjustments for Zithromax® stored in a particular location.
- ▶ Zithromax® 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 Zithromax® 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 on physical inventory) and stock cards should be updated accordingly.
- ▶ Records of all the stock cards should be kept for at least 2 years at each location.

Transfer Form (see Annex 17 for example):

- ▶ This form should be used to issue Zithromax® 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 record keeping 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 Zithromax®.
- ▶ 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 2 years.

2.2.4: Managing Close-Dated Drugs

Like all other medicines, Zithromax® has a specific expiry date.

- ▶ Zithromax® POS has a shelf life of 24 months from the date of manufacture (5 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.

Zithromax® expires on the last day of the month indicated on the bottle.

Zithromax® cannot be distributed after its expiration date!

Actions to take depending on expiration date of Zithromax®

POS	Tablets	Actions to be taken prior to distribution	Actions to be taken during and after distribution
Less than 6 months Category A <i>Urgent action required</i>	Less than 12 months Category A <i>Urgent action required</i>	<ul style="list-style-type: none"> ▶ Separate the lot that is due to expire from other inventories. ▶ Use all the products from this lot first in the distribution. 	<ul style="list-style-type: none"> ▶ 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 <i>Inventory Alert</i>	12 months to 36 months Category B <i>Inventory Alert</i>	<ul style="list-style-type: none"> ▶ Separate these drugs from other inventories. ▶ Use the products of this category after using category A products. 	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ No action necessary. Just follow FEFO policy. 	<ul style="list-style-type: none"> ▶ Complete the post MDA checklist in timely fashion.

2.2.5: Managing Damaged or Expired Drugs

Damaged or expired drugs should NOT be administered under any circumstances. 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. Open bottles of reconstituted POS remaining after the completion of the MDA campaign.
6. Bottles without any 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 Zithromax® is found in any of the six conditions listed above or any other related conditions suggesting damage or expiration, immediately notify the NPC.

2.2.6: Zithromax® 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 Zithromax® from the distribution points back to a centralized storage location at the regional or district level)
 1. Collect empty Zithromax® bottles intended for disposal (or if the bottles are to be re-used for another purpose, make labels unreadable to avoid confusion over the contents of the bottle). The label should be defaced by masking with a permanent black marker.
 2. Return all usable Zithromax® to the regional and district level store as soon as possible after MDA (preferably within two weeks)
 3. Complete the end of Zithromax® campaign physical inventory
 4. Dispose of expired, damaged, or unusable Zithromax® (see section on managing expired or damaged 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 Zithromax® campaign. The distribution report is submitted annually according to MOU. (See **Annex 18** 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 Zithromax® 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.



Sumon Ray for the International Trachoma Initiative



Photo credit: Brent Stirton for the International Trachoma Initiative

3. Supply Chain Assessments

Supply chain assessments are often conducted for countries preparing to receive the Zithromax® 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 Zithromax®. 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 in a timely fashion 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 Zithromax® Supply Chain Assessment Tool available on trachoma.org to perform self-assessments on an annual basis.



A community member in Chimphepo village gets antibiotic treatment during a Mass Drug Administration (MDA) campaign in October 2016. The International Trachoma Initiative manages Pfizer's donation of Zithromax® for trachoma MDA, which is part of the comprehensive SAFE strategy to eliminate trachoma. An estimated 500,000 people in more than 100 communities were offered treatment with antibiotics by the Malawian government and implementing partner Blantyre Institute for Community Outreach (BICO) during this campaign. *Photo credit: Billy Weeks for the International Trachoma Initiative*

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 Zithromax®, 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 attain 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 in this 21st century.

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

Annex 1: Resource Materials	2
Annex 2: World Health Assembly Resolution 51.11 on Global Elimination of Blinding Trachoma	3
Annex 3: Decision Making Flowchart.	4
Annex 4: Decision Tree to Determine Inclusion of Refugee Communities in Zithromax® Requests for MDA.	5
Annex 5: Zithromax® Dosing Guidelines.	7
Annex 6: Serious Adverse Event Reporting	9
Annex 7: Obligations of ITI and the Ministry of Health as stated in the Memorandum of Understanding	10
Annex 8: Zithromax® Shipment Calculation Tool	13
Annex 9: Zithromax® Shipment Contact List	14
Annex 10: Certificate of Donation	16
Annex 11: Pro Forma Invoice	17
Annex 12: Air Waybill	19
Annex 13: Zithromax® Receipt Confirmation Form.	20
Annex 14: Zithromax® Allocation Schedule Form.	21
Annex 15: Zithromax® Inventory Report	22
Annex 16: Zithromax® Stock Card	24
Annex 17: Zithromax® Transfer Form	25
Annex 18: District Level Distribution Summary Report Form.	26

Annex 1: Resource Materials

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

Available from: www.trachomacoalition.org

MDA

- ▶ Preferred Practices for Zithromax Mass® Drug Administration.
- ▶ Micro-planning for Effective Zithromax® Mass Drug Administration.

FE

- ▶ All you need for F&E: A practical guide to partnering and planning.

TRICHAISIS

- ▶ Trichiasis Counseling Guide.
- ▶ Training Curriculum for Trichiasis Case Identifiers.
- ▶ Supportive Supervision for Trichiasis Trachomatous Programs.
- ▶ Organizing Trichiasis Surgical Outreach.

Resource Materials from the World Health Organization (WHO)

Available from: www.who.int

- ▶ Global Scientific Meeting on Trachomatous Trichiasis – Moshi, Tanzania 2012.
- ▶ Second Scientific Meeting on Trachomatous Trichiasis – Cape Town, South Africa, 2015.
- ▶ Fourth Global Scientific Meeting on Trachoma – Geneva, Switzerland, 2018.
- ▶ Validation of elimination of trachoma as a public health problem.

Annex 2: World Health Assembly Resolution 51.11 on Global Elimination of Blinding Trachoma

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 intumed 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 intumed 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;

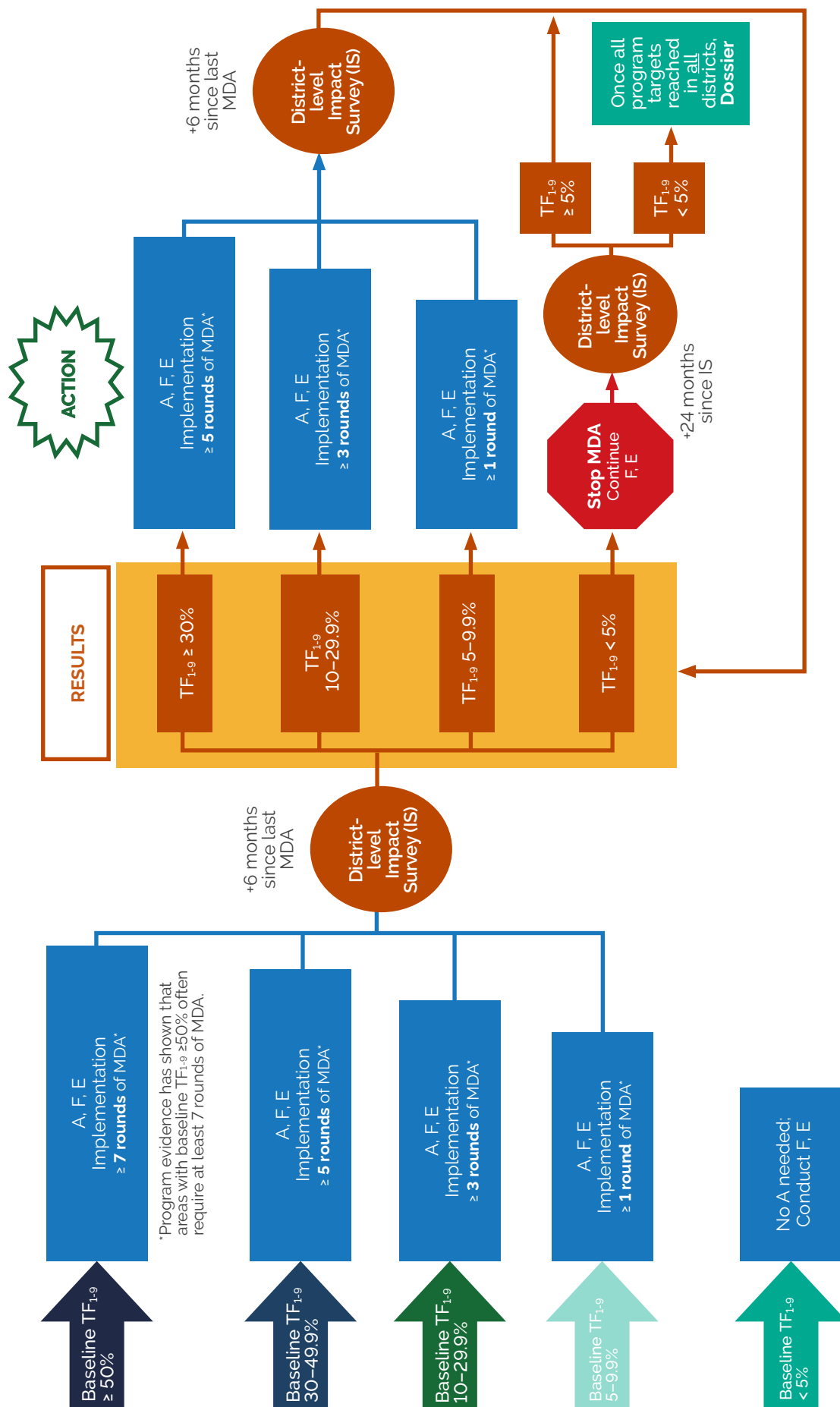
(4) to facilitate the mobilization of extrabudgetary funds;

(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)

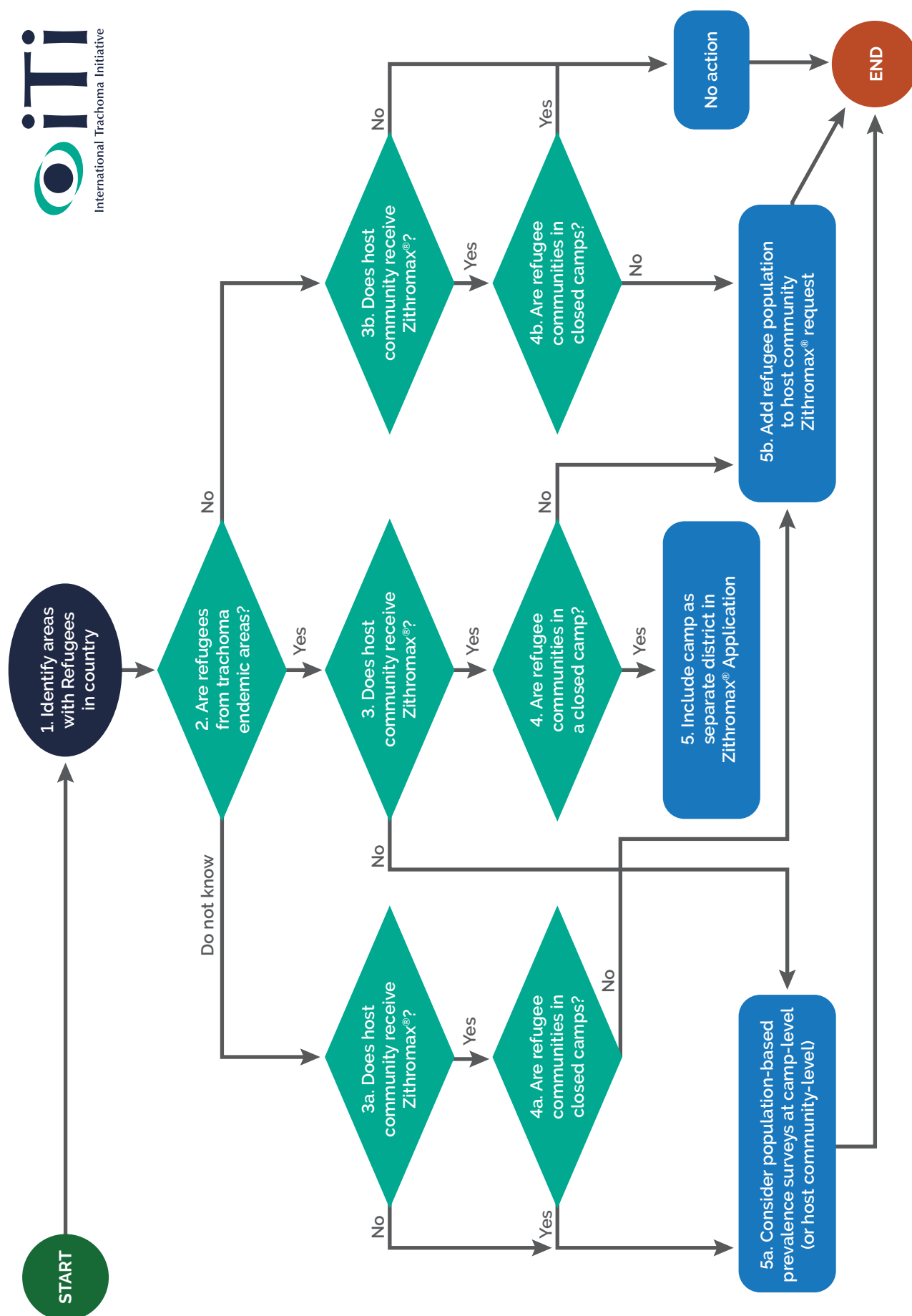
Annex 3: Decision Making Flowchart

Diagram on Decision Making for the Antibiotic Treatment of Trachoma



Annex 4: Decision Tree to Determine Inclusion of Refugee Communities in Zithromax® Requests for MDA

Flow chart to determine inclusion of refugee communities in annual Zithromax® requests for trachoma MDAs



Annex 4: Decision Tree to Determine Inclusion of Refugee Communities in Zithromax® Requests for MDA

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 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 Zithromax® 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 request for Zithromax® from trachoma endemic countries reviewed by the Trachoma Expert Committee during bi-annual meetings organized by the International Trachoma Initiative.

Height- and Age-Based Dosing for Zithromax® POS and Tablets

July 2018

<div>Infants under 6 months: TEO (tetracycline eye ointment)</div> <div></div>	<div>Children ≥ 6 months and < 7 years receiving POS*</div> <div></div>	<div>Tablets</div> <div>Height (cm)</div> <div>> 138</div> <div>120 - 138</div> <div></div>	<div>Children ≥ 7 years and < 15 years receiving tablets</div> <div></div>	<div>≥ 15 years: 4 tablets</div> <div></div>	Adult
Infant	Child		Adolescent		



GOAL

**ZERO SERIOUS
ADVERSE EVENTS
DUE TO CHOKING**



GOAL

**BETTER MANAGING
TREATMENTS TO
CHILDREN**



Zithromax® Dosing Guidelines

July 2018

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)	Powder for Oral Suspension (POS) dosed according to height
Individuals with difficulties swallowing tablets or uncomfortable taking tablets	
Individuals taller than 120 cm <u>and</u> 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 ZITHROMAX®

No child should ever be forced to take Zithromax®.

Distribution sites can be intimidating for children. If the child is uncooperative or anxious, the parent or guardian is the correct person to administer Zithromax® 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 Zithromax® 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.

Annex 6: Serious Adverse Event Reporting

Safety Reporting Requirements for Zithromax® 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)”), and Product Quality Complaints (“PQC(s)”) related to the use of Pfizer drug products, including Zithromax®.
- 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 (AE):** An adverse event is any untoward medical occurrence in a patient administered a Pfizer product or medical device. The event need not necessarily have a causal relationship with the treatment or usage. This includes, but is not limited to:
- Abnormal test findings
 - Clinically significant symptoms and signs
 - Changes in physical examination findings
 - Hypersensitivity
 - Progression/worsening of underlying disease
 - Lack of drug effect
 - Drug Abuse
 - Drug dependency
- 2.2 **At Risk Scenario (ARS):** Circumstances where the report does not include an AE per se, but may lead to an increased risk of an event for the patient. These circumstances include:
- Medication errors
 - Exposure during pregnancy
 - Exposure during breastfeeding
 - Overdose
 - Misuse
 - Extravasation
- 2.3 **Product Quality Complaint (PQC):** Is any written or oral expression of dissatisfaction relative to the physical properties, condition, labeling, potency and/or packaging of a product.

3. Reporting Process

- 3.1 **Reporting Time-Frames:** The Ministry of Health (MOH) shall report all potential AEs, ARSs and PQCs via the Pfizer-directed reporting mechanism **within twenty-four hours of awareness (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 PQCs should be reported, whether or not there is an associated AE.
- 3.2 AEs, ARSs 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.

Annex 7: Obligations of ITI and the Ministry of Health as stated in the Memorandum of Understanding

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:

- a. ITI agrees to provide the Ministry of Health with the number of treatments of the antibiotic Zithromax® that have been approved by the Trachoma Expert Committee (TEC) for the exclusive purpose of trachoma control in approved districts in application year.
- b. District names and quantities of treatments approved by the Trachoma Expert Committee ("TEC") for distribution in a particular year can be found in the Addendum of the MOU. Any subsequent changes to the approved quantities listed in the Addendum will be communicated to MOH by ITI by means of an Amendment to the MOU.
- c. Each calendar year, ITI will send the MOH an updated Addendum, which will outline the details of the drug donation.

2. Obligations of Ministry of Health:

MOH agrees to abide by the following parameters:

- a. Ensure that Zithromax® is not used for research purposes without the prior, full, written approval of ITI or the TEC.
- b. Ensure free entry of Zithromax® 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, taxes, documentation fees, demurrage fees, as well as in-country insurance, warehousing, and inventory management are the responsibility of the MOH.
- c. Ensure that Zithromax® is distributed only in the districts for which the donation is expressly approved as stated above.
- d. Obtain the necessary financial and human resources to support the distribution of the donated Zithromax®.
- e. Implement the full SAFE strategy in the districts in which the Zithromax® distributions occur.
- f. Exclude children under 6 months of age from receiving Zithromax® during distribution campaigns.
- g. 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)"), and Product Quality Complaints ("PQC(s)") that may be associated with Zithromax®, they will inform Pfizer through the designated Pfizer regional offices listed in the contact list on Table 1 of the MOU in

Annex 7: Obligations of ITI and the Ministry of Health as stated in the Memorandum of Understanding

accordance with the procedures for AE, ARS and PQC reporting included in Annex A of the MOU.

- h. Ensure that Zithromax® 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 Zithromax® will be distributed in a non-commercial fashion.
- i. The collection, storage, handling, transportation, movement, disposal, and destruction of all expired Zithromax® donated pursuant to the MOU shall be the responsibility of MOH in compliance with Pfizer's destruction procedures and 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.
- j. Cooperate with ITI, Pfizer, the TEC and their respective affiliated entities and representatives as reasonably required to accomplish the objectives of the MOU. MOH will work with ITI to develop forecasts that will be used to guide the manufacture, shipment, and distribution of Zithromax®, 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 Zithromax®.
- k. Ensure that mass administrations of Zithromax® donated by Pfizer are not conducted concurrently with mass administrations of Zithromax® or oral azithromycin purchased or donated from a different source.

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 Zithromax®.
- 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. The Zithromax® stock-on-hand, quantities, expiry date and the precise location of the Zithromax® stock.

MOH acknowledges and agrees that ITI will enter the data reported by countries into the GET2020 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.

Annex 7: Obligations of ITI and the Ministry of Health as stated in the Memorandum of Understanding

Reports are to be submitted to ITI as follows:

<u>Reporting Period</u>	<u>Due Date</u>
1 January – 31 December 2019	2 March 2020
1 January – 31 December 2020	1 March 2021
1 January – 31 December 2021	1 March 2022

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

4. **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.

5. **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.

Annex 8: Zithromax® Shipment Calculation Tool

Shipment Calculation Tool

Country	Name
Approved - MDA ^(A)	1,080,562
Approved - Surgery or Research ^(B)	6,078
Reserve ^(C)	
Subtotal ^(D=A+B+C)	1,086,640
Reduction % ^(E)	0.05
Reduction ^(F=E*A*C)	54,028
Total ^(G=D-F)	1,032,612

Planned Shipment	POS	TABS	Total
Ratio Requested ^(H)	0.20	0.80	1.00
Treatments Needed ^(I)	205,307	827,306	1,032,613
In Country Inventory Reported ^(J)	1,518	10,731	12,249
Planned Shipment ^(K=I-J)	203,789	816,575	1,020,364

Actual Shipment	POS	TABS	Total
Bottles ^(L=K/4 POS; M=K/166 TABS; round up for a full case)	50,976	4,920	55,896
Cases ^(N=L/48 POS; O=M/24 TABS)	1,062	205	1,267
Pallets ^(N/32 for POS and O/54 for TABS)	33.2	3.8	37.0
Ratio	0.20	0.80	1.00
Treatments ^(L*4 for POS and M*166 for TABS)	203,904	816,720	1,020,624

This shipment will include treatments for:	
District 1	261,153
District 2	265,685
District 3	271,815
District 4	281,909
Total Approved	1,080,562

Annex 9: Zithromax® Shipment Contact List

Zithromax® Contact List (Country Name) 2018 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:

Annex 9: Zithromax® Shipment Contact List

Importer of Record:

NAME

Position

Address

Tel:

Fax:

Email:

Back Page Contact Information (Notes):

(remove or add other contacts as needed)

Notify Contacts:

NAME

Position

Address

Tel:

Fax:

Email:

NAME

Position

Address

Tel:

Fax:

Email:

Annex 10: Certificate of Donation

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 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, 1 200mg of Zithromax® (azithromycin) pediatric 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 Zithromax® (azithromycin) 250mg tablets (red-coated), 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 the 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 Limited (MSL) 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
Director Supply Chain, Corporate Responsibility

www.pfizer.com

Annex 11: Pro Forma Invoice

PFIZER SERVICE COMPANY BVBA Hoge Wei 10 1930 ZAVENTEM BELGIUM		Hyperion Code: 005923 VAT: BE0478242365		PROFORMA INVOICE	
Sold-To - 2000001778 GLOBAL HEALTH SOLUTIONS INC 325 SWANTON WAY UNITED STATES OF AMERICA DECATUR GA 30030		Sales Order No. 5053988219		Invoice No.: 31381411 Billing Date: 08-May-2018 Document Date: 08-May-2018	
		Shipment No.		Customer Order No. 2018 Country #1	
		Terms of Payment No Charge		Incoterms CIP LUSAKA	
		Mode of Transport Air		Letter of Credit	
Ship-To - 2001002313 MEDICAL STORES LIMITED NATIONAL TRACHOMA PROGRAM		Port of Export ZAVENTEM D douanekantoor		Vessel/Flight No.	
		Ship From Country Belgium		Port of Dest. (Vessel, Air Only) Lusaka	
Notify Party -		Shipping Marks 2018 Country Zithromax Shipment #1			
Ship From LSP H.Essers Genk Transportlaan 4, Magazijn 4 3600 GENK BELGIUM					
Item	Material Number	Quantity	Unit Price	Value in USD	
	Material Description	Customs Tariff Code	Country of Origin / Region		
000010	F000146420 ZITHROMAX 250MG 500 TRACHOMA	3.048 EA HS Origin : 3004.20.00 HS Destination: 3004.20	500,00000 / EA Puerto Rico	1.524.000,00	
Exp Date: Donation		Manuf Date: 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 NA Bank Account: 17670230 Bank number: 185008 SWIFT code: CITIGB2L IBAN: GB91CIT118500817670230		

Annex 11: Pro Forma Invoice

PFIZER SERVICE COMPANY BVBA Hoge Wei 10 1930 ZAVENTEM BELGIUM		PROFORMA INVOICE	
		Invoice No.: 31381411 Billing Date: 08-May-2018 Document Date: 08-May-2018	
000020	F000129372	416 CS	273,60000 / CS
ZITHROMAX 1200mg POS 48x1 BTL			113.817,60
		Italy	
		HS Origin : 3004.20.00	
		HS Destination: 3004.20	
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 BOITTLES			
TOTAL ITEM VALUE			0,00
VAT			0,00 %
TOTAL AMOUNT			0,00
FREE ITEMS (INCLUDE IN VFC)			1.637.817,60
<p>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.</p> <p>Article 146,1,a) Council Directive 2006/112/EC - VAT exempt export of goods</p> <p>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.</p> <p>Donee of Record: Williams P. NICHOLS, MPA Chief Operating Officer Global Health Solutions, Inc 325 Swanton Way Decatur, GA 30030 USA Tel: +1 404-592-1430 Fax: +1 404-371-1138 Email: bnichols@taskforce.org</p> <p>Consign To: Dr. Jabbin Mulwanda Permanent Secretary- Health Services</p>			
		Remit To: Name of bank: Citibank NA Bank Account: 17670230 Bank number: 185008 SWIFT code: CITIGB2L IBAN: GB91CIT118500817670230	

Annex 12: Air Waybill

242 BRU 10540880		IC BRU 481017		SVC CDE: AA2		242 -10540880	
Shipper's Name and Address PFIZER SERVICE COMPANY BVBA C/O DGF BELGIUM HOGE WEI 10 ZAVENTEM BELGIUM			Shipper's Account Number BE 1930			Not Negotiable Air Waybill Issued by STABO AIR LIMITED KABELENGA ROAD LUSAKA ZAMBIA	
Consignee's Name and Address MEDICAL STORES LIMITED NATIONAL TRACHOMA PROGRAM PO BOX 30207 MUKWA ROAD, PLOT 644 ZM LUSAKA, ZAMBIA			Consignee's Account Number			It is agreed that the goods described herein are accepted in apparent good order and condition (except as noted for carriage SUBJECT TO THE CONDITIONS OF CONTRACT ON THE REVERSE HEREOF, ALL GOODS MAY BE CARRIED BY ANY OTHER MEANS INCLUDING ROAD OR ANY OTHER CARRIER UNLESS SPECIFIC CONTRARY INSTRUCTIONS ARE GIVEN HEREON BY THE SHIPPER, AND SHIPPER AGREES THAT THE SHIPMENT MAY BE CARRIED VIA INTERMEDIATE STOPPING PLACES WHICH THE CARRIER DEEMS APPROPRIATE. THE SHIPPER'S ATTENTION IS DRAWN TO THE NOTICE CONCERNING CARRIER'S LIMITATION OF LIABILITY. Shipper may increase such limitation of liability by declaring a higher value for carriage and paying a supplemental charge if required.	
Issuing Carrier's Agent Name and City DHL GLOBAL FWD.-BE/RA/00106-01 BRU			Accounting Information BRU481017 FIL 484894 OBD 8064963004/8065159752 WFS B712				
Agent's IATA Code 08-4-7001/1012			Account No.				
Airport of Departure (Addr. of First Carrier) and Requested Routing BRUSSELS							
To LUN	By First Carrier 4E	Routing and Destination		To LUN	By 4E	Currency EUR	Declared Value for Carriage NVD
Airport of Destination LUSAKA		Flight/Date 825 /20	For Carrier Use Only	Flight/Date	Amount of Insurance	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 - AS PER ATTACHED DOCUMENTS							
							X SCI
No. of Pieces RCP	Gross Weight kg	Rate Class Commodity Item No.	Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions of Volume)	
16	2378.0	QGC	2669.0	8.18	21832.42	ZITHROMAX NOT RESTRICTED VOL. 16,013M3 //SLAC-16	
16	2378.0				21832.42		
Prepaid		Weight Charge		Collect		Other Charges P MYC 160.14 P SCC 400.35	
21832.42							
Valuation Charge							
Tax							
Total Other Charges Due Agent						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.	
Total Other Charges Due Carrier						DHL GLOBAL FWD FOR: PFIZER SERVICE COMP MAX PEETERS	
560.49						Signature of Shipper or its Agent	
Total Prepaid		Total Collect				DHL GLOBAL FWD AS AGENT FOR CARRIER STABO AIR LIMITED 19MAY18 BRUSSELS DHL GLOBAL FWD	
22392.91						Signature of Issuing Carrier or its Agent	
Currency Conversion Rates		CC Charges in Dest. Currency				Executed on (date) 19 MAY 2018 at (place) BRUSSELS	
For Carrier's Use only at Destination		Charges at Destination		Total Collect Charges		242 -10540880	

ORIGINAL 2 (FOR CONSIGNEE)

Zithromax® Receipt Confirmation Form

From: _____ (Country name)

To: ITI Supply Chain Manager

This is to acknowledge that we have received the following Zithromax® products on _____ (Date)

Product Description	Number of bottles shipped	Number of bottles received in good condition	Number of bottles damaged/lost	Current storage location
1. Tablets				
2. POS				

Notes about damaged/lost products:

Prepared by: _____
Name Signature

Approved by: _____
Name Signature

Stamp or seal:

Annex 14: Zithromax® Allocation Schedule Form

Zithromax® Allocation Schedule

[illegible]

***Note: Quantities are based on current bottle size**

****Number of bottles of Zithromax® per carton**

Zithromax® for MDA

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

Return email for inventory report: supplychain@taskforce.org

Thank you for not entering any data in the section in yellow. These values are calculated automatically.

[illegible]

Explanation of Terms:

Available/Usable Stock: This is stock that still has shelf life and can be distributed.

Wastage: This is the number of Zithromax® bottles that were wasted during treatment.

Unusable: This is the Zithromax® 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 be usable.

Expired: This is the quantity of Zithromax® bottles that are past their expiry date, and therefore may not be used.

Losses: This is the number of Zithromax® removed from the system for any reason other than consumption (theft, for example).

Adjustment: 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 Zithromax® transfer between locations or a record to be made when differences arise between inventory count & recorded balance.

Comments:

Zithromax® for Surgery

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

Return email for inventory report:

[illegible]

Adjustment- This is a record that is used for Zithromax® transfer between locations or a record to be made when differences arise between inventory count & recorded balance.

Comments:

Annex 16: Zithromax[®] Stock Card

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

SerialNo. _____

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)
Zithromax® tablets			
Zithromax® POS			

Issuer Name: _____

Carrier Name: _____

Issuer Signature: _____

Carrier Signature: _____

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

List of quantity 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)
Zithromax® tablets					
Zithromax® POS					

Note for damaged /lost quantity (if any):

Receiver Name: _____

Carrier Name: _____

Receiver Signature: _____

Carrier Signature: _____

2019 Trachoma Elimination Monitoring Form – Data for 2018

Geography & Population				Survey Data				Surgery				
Region	District	Sub-district	Geoconnect ID	Total 2018 Population	Year of Current Survey	Current TF % (1-9 yrs)	Current TT%	TT Age Group and Sex	Source	2018 Number of Persons Operated on for TT		
?data.admin1_name	?data.admin2_name	?data.admin3_name	?data.geo_id	?data.population	?data.current	?data.current	?data.current	?data.tt_age_group	?data.source	Females Operated	Males Operated	Total Operated (both sexes combined)

Antibiotics															
TT	2018 Number of Persons Targeted for Treatment	2018 Number of Persons Treated with Azithromycin Tablets			2018 Number of Persons Treated with Azithromycin Pediatric Oral Suspension			2018 Number of Persons Treated with Tetracycline Eye Ointment			2018 Number of Persons Treated with Azithromycin Eye Drops			2018 Total Number of Persons Treated	Treatment Coverage % in 2018 (treated/targeted)
		Females Treated	Males Treated	Total Treated (both sexes combined)	Females Treated	Males Treated	Total Treated (both sexes combined)	Females Treated	Males Treated	Total Treated (both sexes combined)	Females Treated	Males Treated	Total Treated (both sexes combined)		

Facial Cleanliness		Environmental Improvement	
118	Methods of Delivery of F SELECT ALL THAT APPLY One selection at a time		Notes/Comments



International Trachoma Initiative

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

