Zithromax® in the Elimination of Blinding Trachoma

A Program Manager's Guide

International Trachoma Initiative

A world free of blinding trachoma.

Acknowledgments

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

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Foreword

Eliminating blinding trachoma by the year 2020 is an achievable yet ambitious goal. Achieving this goal requires the hard work, dedication, commitment and collaborative efforts of a global coalition that includes countless partners from all sectors, at all levels of partnership, from national presidents to village chiefs and local community health care workers. The work of governments, ministries of health, non-governmental organizations, the private sector and communities is essential to the success of the SAFE strategy. At Pfizer, we are humbled by and grateful for the partnerships we have formed over the last eleven years through the International Trachoma Initiative (ITI) to distribute Zithromax® (azithromycin) as a part of the "A" component of the SAFE strategy. We are pleased to be part of the global community that is working to break the cycle of poverty that trachoma imposes on millions of families and communities worldwide.

As we look to the next ten years, we look forward to working hand-in-hand with you and continuing to expand upon that work. This guide has been created by the ITI to help program managers and their partners manage Zithromax® as part of a comprehensive public health strategy to eliminate blinding trachoma. The leadership and dedication of program managers at the national, district and local levels are an inspiration to us all. In turn, we want to respond to and meet the needs of program managers through publications such as this guide. In outlining safe, effective and efficient methods to manage Zithromax® and make it available in local communities, the guide is a critical tool to assist countries developing trachoma programs for the first time. For continuing countries, it will be invaluable as they scale-up their drug distribution capabilities alongside their SAFE activities. With this guide in hand, we will move together toward our shared vision of a world without trachoma.

At Pfizer, we endeavor to effectively utilize our global resources to improve health and well-being at every stage of life. As stewards of Pfizer's Investments in Health platform for corporate responsibility, we utilize the full range of these global resources including medicines, funding, and employee expertise to specifically help those people most in need. By working in partnerships to help address pressing health care issues, such as blinding trachoma, we believe that together we can make a difference for all who rely upon us.

We look forward to continuing our support and working through the International Trachoma Initiative and The Task Force for Global Health to provide the necessary Zithromax® in the effort to eliminate blinding trachoma by the year 2020 and help restore the health and well-being of families now and for generations to come.

On behalf of the Pfizer colleagues in 150 countries around the world, I thank you for your partnership and continued efforts in this shared mission.

— *Caroline Roan*
Vice President, Corporate Philanthropy, Pfizer Inc.
April 2010

PFIZER, INC: WORKING TOGETHER FOR A HEALTHIER WORLD™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com

Wyeth is now a wholly owned subsidiary of Pfizer Inc. The merger of local Wyeth and Pfizer entities may be pending in various jurisdictions and is subject to completion of various local legal and regulatory obligations.

ITI Vision

A world free of blinding trachoma.

ITI Mission

To eliminate blinding trachoma by 2020 through managing the Zithromax® donation and collaborating with partners for the implementation of the full SAFE strategy

A mother in Ethiopia washes her child's face.

From The Director

As the new team at the International Trachoma Initiative met with partners over the last year, we realized that a new guide was needed for trachoma country program managers. With responsibility for implementing and evaluating Mass Drug Administration of Zithromax,® they and their partners would benefit from an updated and clearer description of best practices.

This guide provides a range of practical advice and useful information, from the basics of how to make and use dosing sticks to creating a drug delivery strategy and forming a Community-Directed Distribution Team, from clarifying requirements of the annual application process to highlighting best practices of receiving, storing, and tracking the distribution of donated Zithromax.® In addition, we have included updated forms related to each stage of the work.

As ITI scales up its efforts, we will continue our engagement with national trachoma control programs until they reach elimination. As these countries apply to come into the Zithromax® donation, this guide will serve as an essential document for management of the Zithromax® donation.

Eliminating blinding trachoma by 2020 is possible. But our goal will only be reached through strong and effective collaborations. In that spirit, we offer this guide to all our partners and hope that they will find it useful in their important work.

— Dr. Danny Haddad, Director,
International Trachoma Initiative
April 2010

A woman in Sudan uses a dosing stick for mass administration of Zithromax.®

Face washing is a key activity in the prevention of trachoma.

Introduction

The International Trachoma Initiative (ITI) was founded in 1998 in response to the World Health Organization's call to eliminate blinding trachoma by the year 2020 (GET2020). ITI's founding partners, Pfizer and the Edna McConnell Clark Foundation, saw the need for an international nongovernmental organization dedicated solely to preventing blinding trachoma.

To support achievement of that goal, ITI collaborates with governmental and nongovernmental organizations at the local, national, and international levels to support the WHO-recommended SAFE strategy for trachoma control (Surgery; Antibiotics; Facial cleanliness; and Environmental improvement).

In April 2009, ITI joined forces with the Task Force for Global Health to leverage resources and significantly scale up efforts to eliminate blinding trachoma.

ITI is a partner among partners and seeks to engage in dialogue with development and public health practitioners to support program implementation and the goal of elimination.

1.0 Purpose of Guide

This manual has been written for use by trachoma program managers and other partners in order to support and guide the planning, implementation, and evaluation of the antibiotic component of the SAFE strategy. While antibiotics alone will not eliminate blinding trachoma and sustain its elimination, the generous donation of Zithromax® by Pfizer Inc. is enabling countries to move forward more quickly towards their elimination goals. Alternative antibiotic therapies are available for endemic countries that are not included in the ITI program. This guide, however, was written especially for Pfizer Inc.'s donation of Zithromax®.

The drug donation also allows the global trachoma community to mobilize the additional resources and support necessary in order for the goal of GET2020 to become a reality. This guide supports the Zithromax® management aspect of ITI's mission statement:

"To eliminate blinding trachoma by 2020 through managing the Zithromax® donation and collaborating with partners for the implementation of the full SAFE strategy."

A man and child stand next to a POS height-dosing stick.

1.1 Trachoma

Trachoma is the world's leading cause of preventable blindness. An estimated 8 million people are already blind or visually impaired because of the disease, and 84 million have active infection and need treatment. More than 10 percent of the world's population is at risk of blindness due to trachoma, which has incapacitated families and communities for centuries in the poorest regions of Africa, Asia, the Middle East, and in some parts of Latin America, Australia, and Asia.

The disease is caused by repeated infection by the bacterium *Chlamydia trachomatis*. Trachoma is spread through contact with infected people (discharge from the eyes and nose can easily transmit the disease). Flies that seek out the red, sticky eyes caused by trachoma can also transmit the disease from person to person. The disease generally occurs in poor communities where people have limited access to water, sanitation, and primary health care.

Trachoma has an immense impact, globally and in the communities where it is endemic. Trachoma can ruin the economic well being of entire families and communities,

and can affect an individual at any point in their lifetime. Women are two to three times more likely than men to be blinded by trachoma because of, in part, their roles as the primary caregivers of children. 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. If many adults in a village become blind from trachoma, an entire community may be debilitated. Without intervention, trachoma keeps families shackled in a cycle of poverty as vulnerability to the disease and its effects are passed from one generation to another.

Normal Eyelid

Trachomatous Inflammation — Follicular (TF): The presence of five or more follicles of at least 0.5 mm in the upper tarsal conjunctiva.

Trachomatous Inflammation — Intense (TI): Pronounced inflammatory thickening of the tarsal conjunctiva that obscures more than half of the normal deep tarsal vessels. (Photo shows TF and TI.)

Trachomatous Scarring (TS): Presence of scarring in the tarsal conjunctiva.

Trachomatous Trichiasis (TT): At least one eyelash rubs on the eyeball, or there is evidence of recent removal of in-turned eyelashes.

Corneal Opacity (CO): Easily visible corneal opacity over the pupil.

The World Health Organization standardized grading system for trachoma.

Trachoma is included in a group of diseases commonly referred to as neglected tropical diseases or NTDs. Due to existing resources, trachoma control activities are often integrated with other NTD control efforts, particularly by synchronizing rounds of Mass Drug Administration (MDA).

1.2 Progression of the Disease

There are five distinct grades of trachoma, which have been categorized in a grading scale by the World Health Organization (see Figure). Only the last grades, trachomatous trichiasis (TT) and corneal opacity (CO), are clearly visible without examining the inside lining (conjunctiva) of the upper eyelid.

Trachomatous inflammation follicular (TF), trachomatous inflammation intense (TI), and trachomatous scarring (TS), can be identified only by turning up the upper lid and examining the conjunctiva. It is not possible to identify these grades of trachoma by simply looking at the eye.

When a person's eyes are infected with *Chlamydia trachomatis*, the bacteria develop in the cells of the conjunctiva. This infection usually results in the development of inflammation and of a few follicles under the upper eyelid. Some cases are mild and get better in a few weeks or months. However, repeated infection causes more inflammation (grade TF and if severe TI). The signs of moderate/severe active disease (grades TF and TI) are most commonly seen in children.

The cycle of active infection and resolution repeated over many years leads to the development of scars on the conjunctiva (grade TS). Scarring is not a sign of active infection, but rather indicates that an individual has had

To combat trachoma, the World Health Organization has endorsed an integrated strategy known as SAFE.

Surgery for people with trichiasis at immediate risk of blindness

Antibiotic therapy to reduce the community reservoir of infection and therefore stop transmission

Facial cleanliness and improved hygiene to reduce transmission

Environmental improvements, particularly water and sanitation, to make living conditions better so that the environment no longer facilitates the maintenance and transmission of trachoma

repeated trachoma infections in the past. Scarring is more common in adults, but may occur in teenagers or even children in trachoma hyper-endemic areas. As active infections lead to more scarring, the scars contract over time, shortening the eyelid. This shortening distorts the lid margin, pulling the eyelashes inward. If left untreated, recurrent scarring of the eyelid causes the eyelashes to turn inward and rake the cornea. This is called trichiasis (grade TT) and is seen typically in adults, although cases do occur in children. Trichiasis is painful as the lashes rub against the transparent part of the eye (the cornea). The constant rubbing of the lashes scratches the cornea and other infections can also develop. The combination of the scratching and infection finally turns the cornea opaque, and the individual loses vision (grade CO). Patients may report some improved vision after trichiasis surgery, which reverses the in-turning of eyelashes.

1.3 The SAFE Strategy

The SAFE strategy is the recommended approach of the World Health Organization (WHO) for attaining the control and eventual elimination of blinding trachoma. Linking treatment with prevention and strengthening the infrastructure for health and hygiene, the SAFE strategy sees to the immediate needs of those at imminent risk of blindness while attending to the root cause of the disease. By addressing the medical, educational, and social determinants of disease, the SAFE strategy provides the structure to achieve the GET 2020 goal of global elimination of

Trichiasis surgery

blinding trachoma by 2020. It is crucial that all components of the SAFE strategy are implemented in synergy as trachoma cannot be sustainably eliminated with antibiotics alone.

1.3.1 SURGERY

Surgery is the usual treatment for trachomatous trichiasis (TT), the immediate precursor to blindness. Surgery is the first component of the strategy, because it addresses the needs of those at imminent risk of blindness and because its tangible benefit can provide a basis of credibility for preventive activities. The WHO has endorsed a simple and cost-effective surgical procedure that rotates eyelashes away from the eye and thus prevents further scarring on the cornea.

Ophthalmic assistants and nurses can be trained to perform the surgery using local anesthetic. Training takes approximately two weeks. The procedure itself takes about 15 minutes and long-term success rates for the procedure are approximately 80 percent.

The best place for providing surgical services is at the community level. Trichiasis is most common in women aged 20-60 years. These women may not be aware of treatment options, nor have easy access to these services. The surgical component of the SAFE strategy therefore requires both outreach services and health education.

Girl taking a dose of Zithromax®

1.3.2 ANTIBIOTICS

Antibiotics treat active disease (TF or TI). The antibiotic component of the SAFE strategy aims to suppress transmission in the community by treating the pool of infection found in specific groups of individuals. Before Pfizer began its donation of Zithromax® for trachoma control, tetracycline eye ointment was the antibiotic component of the SAFE strategy.

As a topical preparation, however, tetracycline does not treat the extra-ocular reservoirs of infection associated with return of disease, and its six-week long treatment schedule led to poor compliance. Zithromax® is now available as a global donation through the International Trachoma Initiative from Pfizer Inc.

A boy in Nepal washes his face.

1.3.3 FACIAL CLEANLINESS

Water use and availability are important determining factors in the transmission of trachoma. Facial cleanliness, even more than the other components of the SAFE strategy, relies on health education. Health educators have to promote the development and dissemination of effective messages for people to change behavior. Creative methods to change the behavior of children and their caretakers have been tested, such as the "child to child" approach, using older children to influence the behavior of pre-school children and school programs to educate the next generation of caretakers. Because behavioral changes can be difficult to achieve and sustain, control and prevention activities must be designed, planned and implemented with the participation of the communities, especially women, as they are often the caretakers for the children from the onset.

1.3.4 ENVIRONMENTAL IMPROVEMENT

Environmental improvement is part of the overall process of community development, and there are many environmental factors that can cause or prevent trachoma. In addition to increasing access to water availability and utilization, the management of human waste is important. Trachoma elimination programs

The "E" component of SAFE aims to reduce transmission of C. trachomatis *by promoting better environmental hygiene.*

world-wide are involved in provision of water and construction of household latrines in order to address these needs in the most endemic areas. The scope of this component is so broad that collaboration beyond the health sector is critical. Improvements in water and sanitation will not only facilitate trachoma control, but will also have effects that go further. It is therefore important to coordinate any environmental activities with the Ministries of Water and Sanitation and other development agencies involved with the same issues. To have an impact, these improvements must be technically sound, politically feasible, and socially acceptable.

2.0 Mass Drug Administration (MDA) Strategy

2.1 Eligible Population

In each community, treatment teams should aim to achieve the highest coverage of the population as possible and certainly no lower than 90% coverage, which is defined as the number of people treated (with either Zithromax® or tetracycline eye ointment) divided by the total number of residents. Studies have shown that when coverage is higher than 90% and approaching 100%, there is a reduced chance for recurrence of infection before the next round of annual treatment.

With few exceptions (see below), all residents of the targeted communities should be offered an antibiotic. Parents of children under 6 months of age should be given 2 tubes of tetracycline eye ointment, shown how to apply it and instructed to do so to both the child's eyes twice daily for 6 weeks. All individuals older than 6 months should be offered a single oral dose of Zithromax® (if available) at a dose determined by their height.

People waiting in line to receive Zithromax.®

Adults or children with disorders that prevent full extension of the body and limbs should be given the same dose as someone of similar age and build.

While it will remain the decision of national authorities whether and how to use the drug, Pfizer has reached the conclusion that for pregnant women at risk of trachoma the benefits of treatment with Zithromax® outweigh the risks to both mother and fetus. This assessment is based on recent research studies and prevailing medical practice. For pregnant women vulnerable to trachoma, the documented benefits of treatment outweigh the potential but undetected risks to the fetus.

The implication of this policy is that ITI supported programs now have three options with respect to the treatment of pregnant women.

1. Provide pregnant women with treatment by Zithromax®.

2. Provide pregnant women with an alternative treatment, e.g. tetracycline eye ointment.

3. Provide pregnant women with counseling to receive treatment as soon as possible post partum.

2.2 Distribution Duration and Frequency

ITI will provide enough antibiotic for a country program to achieve a 100% coverage rate but an acceptable coverage rate would fall between 90-95% of the eligible population.

Please see the World Health Organization's web site at http://www.who.int/topics/trachoma/en for its manual "Trachoma Control: A Guide for Programme Managers" for guidelines of starting and stopping antibiotic treatment (page 21). These guidelines are also found in Section 8.1 of this guide. The current WHO guidelines for antibiotic treatment indicate that MDA should be carried out annually for 3 years before a repeat prevalence survey. Recent findings suggest that up to 5 years of MDA may be necessary in areas with a high burden of disease before surveying for impact. For this reason, ITI and its Trachoma Expert Committee are prepared to receive requests from countries for Zithromax® for such meso- and hyper-endemic areas. The TEC has recommended that districts with a baseline prevalence of TF ≥40% conduct an impact survey after 5 years of implementing the full SAFE strategy. Meso-endemic districts (15-39% TF prevalence) should conduct an impact survey after 3-5 years of full SAFE strategy implementation, depending on the context of the district. Those districts with less than 15%, but more then 10% TF prevalence should plan an impact survey after 3 years.

2.3 Treatment Approach: Integrated Versus Vertical

As a result of common overlap and similarities in treatment strategies, many Neglected Tropical Disease (NTD) programs — including trachoma, lymphatic filariasis, onchocerciasis, schistosomiasis, and soil-transmitted helminthiasis — are "integrating" program components in an effort to increase cost efficiencies, accelerate program scale-up, and improve program coverage. When integrating NTD programs, the key activities that are integrated are typically related to mass drug administration.

Another example of 'integrated' programs is the combination of trachoma and malaria activities (during 'MALTRA' weeks in Ethiopia, for example) in which

People wait at a central distribution point to receive Zithromax.®

Zithromax® is distributed while health education, bednet distribution, latrine construction, and other related activities take place together during a week-long health campaign.

For trachoma, although there are important benefits to integrating with other health programs, it is important that all aspects of the SAFE strategy (beyond just the "A" component) are being addressed in each endemic area. Additional partners should be sought to assist in the delivery of the other program components to populations in need, including water and sanitation programs and school health programs for face washing education.

2.4 Drug Delivery Strategy

Managers should plan Zithromax® delivery strategies appropriate for local conditions. A number of approaches may be adopted:

- **House-to-house administration:** The community-directed distributor (CDD) collects the drug from a designated center and goes from house to house to administer the antibiotic. This approach ensures coverage of all households but is labor intensive, especially in areas where population density is low and household members might not be present during the time of drug distribution.

- **Central point distribution:** Drug distribution points are set up at sites selected to be accessible to the community. CDDs administer the antibiotics to beneficiaries who come to the central point. Supplying drugs and ensuring potable water at a central point involves increased logistics.

A young boy transports potable water to a central distribution point.

- **Administering drugs in special population groups:** Certain population groups can easily be reached at particular locations: students in schools, patients in hospitals, workers in commercial establishments, major building sites, industries, prison inmates, and displaced persons in refugee camps.
- **Areas of community aggregation:** Market places, bus and railway stations, fairs and festivals, religious gatherings, and other sites where people congregate can also be used to reach the community.
- **Urban distribution:** If an urban district is found to have a TF rate of greater than 10% in children, MDA can be authorized in that urban area.

The mass drug administration may be organized as a national day or a week with an intensive campaign approach. If such a focused approach cannot be adopted due to logistical constraints, the distribution could be staggered over a period of 1 to 4 weeks. The period of the campaign should be acceptable to both the health authorities and the communities. Communities, through their representatives, should be involved in decisions on the timing of drug distribution at local levels. Mass drug administration through a community-directed approach has been found feasible in Africa, where the communities make decisions on the timing and choose the CDD, with the health services playing a supportive role.

Pre-Treatment Checklist for District Level Program Managers:
☐ Community leadership has been consulted and are involved with planning and implementing the MDA campaign
☐ Census has been completed
☐ Zithromax® has been delivered and stored in local facilities
☐ Dates for distribution have been established
☐ Health education messages and activities are planned
☐ Data collection forms are prepared, sorted and counted (see Appendix for district level distribution summary form)
☐ System for referring trichiasis surgery cases has been established
☐ Height-dosing sticks are ready
☐ Distribution teams have been trained
☐ All treatment teams are aware of their responsibilities
☐ Supplies such as potable water and drinking cups for swallowing tablets are on hand
☐ Vehicles have been serviced and adequate petrol is available
☐ Plan for return of unopened bottles or opened bottles of Zithromax® is in place
☐ Once the health care workers or community-directed distribution team has completed a round of treatment, particularly as a program first gets underway, a review session should be conducted to review program experience and make adjustments accordingly.

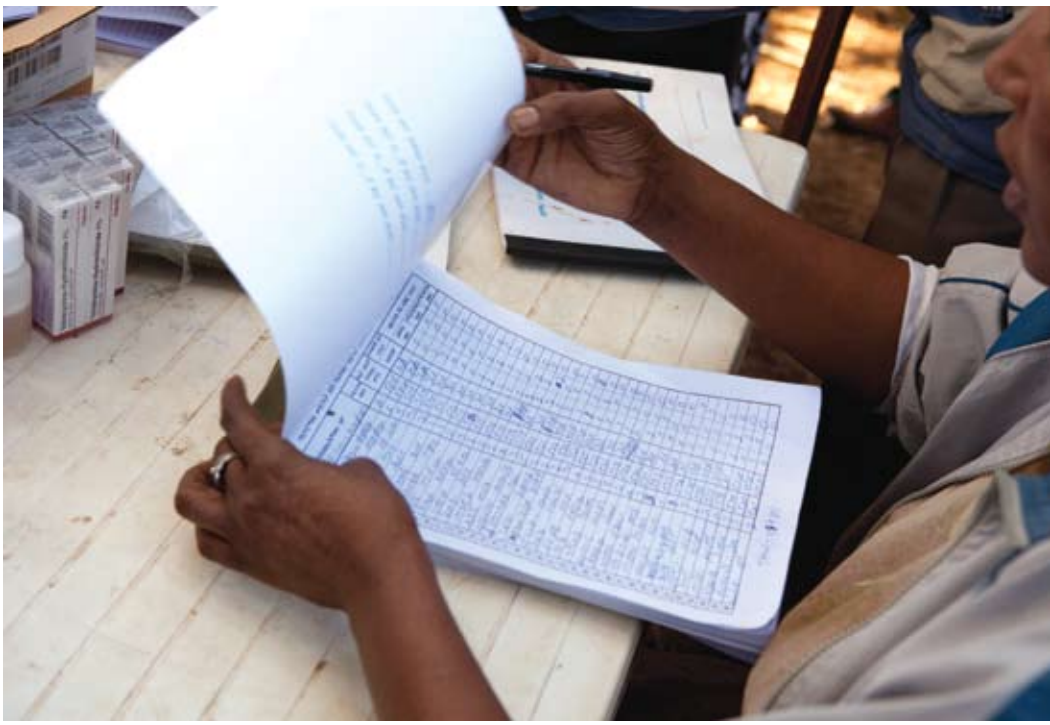
2.5 Training of Community-Directed Distributors

Training of CDDs is important to harmonize the mass distribution of antibiotic in the country. The trained personnel will also train the distribution campaign team at the village level based on the below-mentioned job description of participants. The training period will take 1-2 days. The distribution teams should be trained to perform the following tasks as well as others that are locally determined:

- Prepare and educate communities about trachoma, SAFE as a whole and, particularly, antibiotic treatment.
- Measure everyone using a height-dosing stick.
- Mix and administer Pediatric Oral Suspension (POS) including removal of child-safe bottle caps.
- Keep records on the forms or registers provided.
- Monitor and report on serious adverse experiences.

2.6 Census

A census is necessary in forecasting antibiotic need and in ensuring a program has an accurate coverage rate. Achieving a high antibiotic coverage is critical to the effectiveness of the 'A' component of SAFE. To help achieve high coverage (and to show that it has been achieved), an accurate census of the population to be treated is required. Leaders of communities endemic with trachoma should be consulted about the best way to prepare the census. Literate community members should be involved, with supervision by local health workers or teachers. The information collected from each household should include the name of the head of the household and the name, date of birth, and sex of each person normally resident there. Specific mention should be made of any member of the family who is temporarily absent from the village or migrants who have come into the village. The names of persons arriving at the central site or found by house-to-house teams should be checked against the community census record. The names of persons who have immigrated (and who intend to live in the community for the following month) or who were born after the census should be



An accurate census is critical to achieving a high rate of antibiotic coverage.

added to the census. Persons who have died or emigrated since the census should be identified by a note in the census record.

A record of census data should be kept on cards, in books or in some other durable format, so that the census need only be updated for the following rounds of antibiotic treatment, rather than being conducted anew. (The census and treatment form in the Annex provides a template.) Census records should be held in a secure place so that they are readily available for the next round of treatments.

On all subsequent censuses, new registration information should be recorded on a separate page and include:

- Children born since the first census was completed
- Women newly married into a family and coming from another village
- Any family members overlooked when compiling the first census
- Any family members who have died since compiling the first census
- Those who may have emigrated or immigrated since the first census

2.7 Community Sensitization

In conjunction with the census exercise, program staff are to educate the community about trachoma and inform them of the reason for antibiotic treatment, the dates and methods of treatment, and the inclusion and exclusion criteria for receiving antibiotics.

The community should be informed about the following as well as additional appropriate, locally determined Zithromax®-related messages:

A CDD team member dispenses Zithromax® to a woman and her child in Ethiopia.

- Trachoma prevention
- The reason for antibiotic treatment
- Excellent safety profile of Zithromax® in preventive chemotherapy interventions
- Dates and methods of treatment and the inclusion/exclusion criteria
- The fact that Zithromax® will be provided free of charge
- The importance of face washing and environmental improvement components of SAFE

An additional visit should be planned for program staff to visit the targeted communities at least one to two days before treatment to confirm arrangements with community leaders and to reinforce health education messages. With the support of program managers, community organizers should finalize plans for trachoma education sessions and attend to arrangements for any educational activities to take place in conjunction with

treatment. These activities, whether performances by theater groups or video screenings, should support and complement the distribution. Advocacy events also can be held the evening or morning preceding treatment.

A CDD team member uses a megaphone to announce Zithromax® MDA information.

2.8 Community-Directed Distribution Team Personnel and Responsibilities

The distribution team number and structure depends on factors such as the strategy of antibiotic distribution, population size, terrain of the land, and local logistics.

The district level program manager is the overall coordinator for the distribution of antibiotics. A field supervisor can assist in monitoring the activity of community distribution teams.

Each treatment team should consist of at least two people:

- **Team leader** — One or two dispensers (who might be a health worker, village chief, or volunteer)
- **One Assistant** (a community health agent, women's group leader, trachoma volunteer, village man or woman)

Managers should consider the following duties and responsibilities of personnel involved in the coordination and distribution:

School children learn about trachoma.

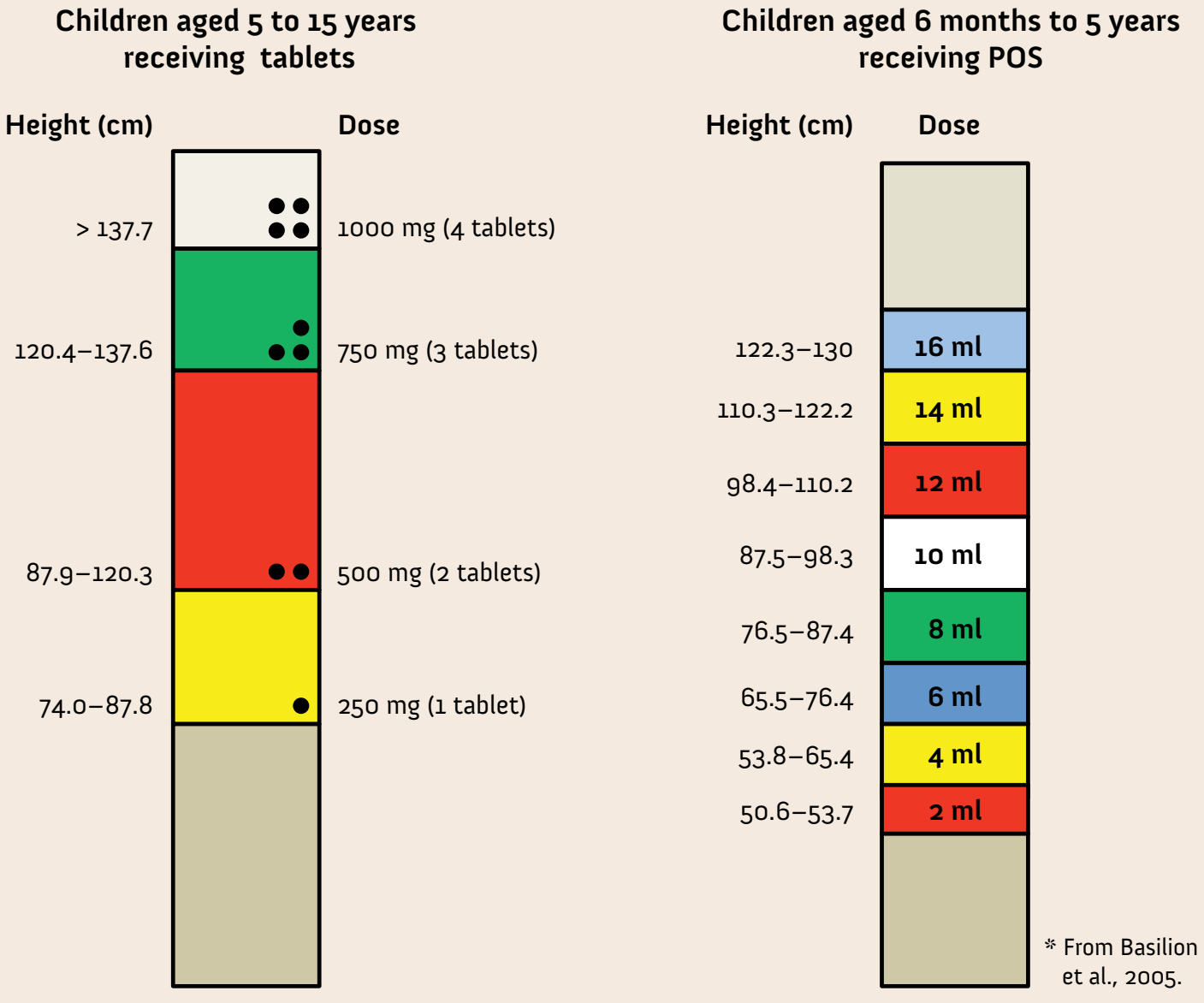
Personnel	Responsibilities
District Level Program Manager	• Coordinates the overall distribution of antibiotics • Trains the community-directed distribution team • Coordinates the overall logistics and supply for the distribution • Liaise with local media to publicize MDA • Ensures the drug is delivered at the temporary store on time • Assigns responsibilities to supervisors and the teams to be involved in the distribution • Reports and investigates all adverse experiences ensuring communication to the country program manager • Approves drug quantity before given to the CDD team
Field Supervisor	• Monitors the activities of 5–10 CDD teams • Ensures that the distributors have the right documents (census), materials and drugs before they leave the central distribution point • Distributes received drugs to the dispensers • Ensures that the CDD teams are working in their respective communities as per schedule • Supervises that all eligible people are taking the drug • Facilitates the work of the distribution team by solving problems encountered during the day • Monitors drug balances prepared by dispensers each day and assists dispensers to calculate coverage of the distribution • Reports and investigates any adverse experiences • Checks drug balance at the end of the distribution
Dispenser (Health Worker)	• Leads the CDD team at the community level • Takes the drug from the field supervisor as per the census of the given community population • Makes sure that they have the proper census list • Ensures (with the support of community members) that each person has come with the household head and family • Makes sure that each person is getting treatment as per the census registry • Supervises the proper measurement of height • Observes that everybody swallows the drug • Checks that everybody on the census registry has come and has taken the drug • Reports all adverse experiences to the field supervisor • At the end of each day, calculates balance of issued drug from the field supervisor and then signs with the assistant on the balance sheet
Assistant health agent/women's group leader)	• Informs the community one week in advance, and one day before the distribution date about the distribution schedule and the drug • Informs community members to bring drinking water to be used for swallowing drugs • Ensures that every community member indicated in the census registry has come to get the drug • Identifies the person who comes to take the drug is in the census registry and is a member of that household • Makes sure that peace and order are in place in the distribution areas • Takes the height measurement correctly and directs person and document to the dispenser • Assists the dispenser in making the drug balance at the end of each day and signs with the dispenser on the balance sheet

3.0 Distribution

3.1 How to Make Height-Dosing Sticks

All persons 6 months of age and older should be offered a single oral dose of Zithromax® at a dose determined by their height. (See page 7 for details on exceptions.)

- Children aged 6 months to 5 years (or those weighing less than 15 kgs) should receive Zithromax® POS.
- Children over the age of 5 years who can swallow tablets and adults should receive Zithromax® tablets.



* From Basilion et al., 2005.

Standardized Height-based Treatment Schedule for Zithromax® POS and Tablets*

A young girl's height is measured for Zithromax® treatment.

3.2 How to Use Height-Dosing Sticks

Height-based dosing is a generally accepted and reliable alternative to weight-based dosing for Zithromax® when used in trachoma-endemic countries. A height-based treatment schedule has been developed based on studies that show that height can determine dose safely and effectively. Wooden dosing sticks indicate the correct dose of Zithromax® in number of tablets or milliliters of POS.

Height-dosing sticks should be painted on pieces of lightweight wood about 180 cm long, 4 cm wide, and 1 cm thick. Each dosing section should be painted a different color (using oil based paint) to distinguish clearly between height ranges. The appropriate number of tablets can also be painted on each section, in black or white, to clearly mark the dosing schedule for those administering the tablets.

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 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.

Preparing POS

3.3 Preparing Pediatric Oral Suspension (POS)

POS will be given to children who weigh less than 15 kg. Children who weigh more than 15 kg normally receive Zithromax® tablets. However, children weighing more than 15 kg who have difficulty swallowing tablets can be treated with POS.

Since children are usually more willing to take medicine from their mothers than from strangers, experience suggests that it is helpful to hand the cup to the child's mother to let her give the Zithromax® to the child.

Although many children and their mothers expect that all antibiotics may not taste good, Zithromax® has a sweet cherry-vanilla-banana flavor and children readily swallow it. The parent can offer a drop of the solution for children to taste if they seem initially reluctant.

3.4 Tips for Using POS:

- 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 5 ml of potable water, replace the cap and shake. Then add an additional 10 ml of water. The 15 ml of water plus the Zithromax® powder will make a total of 30 ml of POS.
- The date of reconstitution should be written on the label of any bottle of suspension not finished on the day it is made up, and such bottles must be used before new ones are prepared for the next day.

A young child is given POS.

- After mixing, POS should be kept in a cool place and out of direct sunlight.
- Any suspension that has not been dispensed within 5 days of reconstitution should be discarded.
- POS may be given to older children in case of shortage of tablets.
- Zithromax® tablets and suspension are administered under supervision (taken by the individual in front of the dispenser).
- In order to facilitate measuring of POS, a syringe can be used. Syringes are not provided by Pfizer, however: measuring cups are provided with each carton of Zithromax® POS.
- Measuring cups provided by Pfizer are marked in 5 ml increments. Dispensers should try to measure, as exactly as possible, the proper dosing of POS based on the height-based dosing schedule.

3.5 Side Effects

Zithromax® is well tolerated with a low incidence of side effects. Communities undergoing treatment should be informed in advance that some people will have these reactions. However, these mild reactions do not indicate that the drug is harmful. Encouraging families to eat breakfast on the day of treatment may help prevent stomach problems. Individuals who experience mild side effects should be reassured that their symptoms do not mean they should not take Zithromax® in subsequent treatment rounds.

3.6 Serious Adverse Experiences (SAE)

A serious adverse experience (SAE) is defined as an adverse experience following treatment with a drug that results in any of the following:

- Death
- Life-threatening condition
- In-patient hospitalization or prolongation of an existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly or birth defect
- Cancer
- Overdose (accidental or intentional)

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in the definition above: Such events should also be reported.

Communities undergoing treatment should be instructed what to do if they encounter serious adverse reactions to the antibiotics even though serious adverse reactions to Zithromax® are extremely uncommon. If any occur, community-directed distribution team members should ensure that the persons visit a nearby health institution for immediate care. Such reactions should also be reported, in detail, to the country program managers, who are required to report the experience to ITI within 48 hours of occurrence on the Serious Adverse Experience form provided in the Annex. The emails to which any SAEs should be reported are Dr. Danny Haddad, Director of ITI at DHaddad@taskforce.org and Lisa Rotondo, Associate Director of ITI at LRotondo@taskforce.org. ITI telephone: +1-404-371-0466 and ITI fax: +1-404-371-1138

3.7 Dealing with Rumors and Refusals

If unfounded rumors arise that might keep individuals from receiving treatment or damage the reputation of the MDA campaign, it is important to first analyze the situation and move quickly to respond. Clarify the extent of the rumor or misinformation (type of messages circulating, source, persons, or organizations spreading the rumors) and determine the motivation (lack of information, questioning of authority, religious opposition, or other).

Community members hear health education messages and Zithromax® distribution information broadcast over the radio.

Be proactive in implementing ongoing activities and in increasing communication in advance of the MDA to prevent and limit rumors. 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. Disseminate consistent messages to the community and take the time to deal with rumors as doing so will benefit the MDA campaign in the immediate and future perspective.

An individual should never be forced to take a dose of Zithromax®. As with the case of dealing with rumors, individuals should be educated in advance about the MDA campaign and the benefits of receiving Zithromax® for the treatment of blinding trachoma. Program staff should explain that because trachoma is easily transmitted from one person to another it is important to suppress transmission in addition to curing individuals by achieving a high rate of coverage of all residents in endemic communities. However, if an individual does not wish to take Zithromax®, their right to refuse the drug must always be acknowledged and respected.

3.8 Supervision of Distribution

Supervision of the CDDs is required in all MDA campaigns. The primary role of the supervisor is to support the distribution team. The supervisor's task is to assess the distribution exercise, the work of the CDDs, and to gather information on any cases of serious adverse reactions after taking the drug.

In particular, the supervisor should review the entries in the registers to ascertain if each CDD has maintained appropriate records. In order to facilitate or make the team's efforts productive, supervisors must also assist with any logistic needs the team may have. This includes ensuring that extra forms, additional Zithromax®, and other supplies are available.

Supervisors are expected to report back to district, regional, and country level program managers regarding the successes and obstacles the distribution has been encountering so that they may be addressed in a timely fashion.

4.0 Reporting

Post MDA Checklist:
☐ Return all usable Zithromax® to the district or regional pharmacy
☐ Collect empty Zithromax® bottles for disposal or if the bottles are to be re-used for another purpose, thoroughly make labels unreadable to avoid confusion over the contents of the bottle. The label should be defaced using a permanent black marker. (Labels cannot easily be removed so deface the bottles.)
☐ Complete the end of Zithromax® campaign physical inventory
☐ 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
☐ Combine all data forms and report total number of treatments distributed to the country program manager
☐ The country program manager is required to report final distribution figures to ITI within 90 days of completion of the Zithromax® campaign. (See Annex for District Level Distribution Summary Report form.)

Accuracy and timeliness in reporting are essential for the success of a country program.

4.1 Country Program Quarterly Reporting to ITI

As part of the annual agreement for the Zithromax® donation, country program managers are required to report on a quarterly basis to ITI on the distribution of Zithromax®. Reports are due according to the following schedule:

Quarter 1 (January through March) due May 15

Quarter 2 (April through June) due August 15

Quarter 3 (July through September) due November 15

Quarter 4 (October through December) due February 15

A new form has been developed for countries to use for their quarterly reports to ITI (see Annex for Sample Quarterly Report form). An electronic version of this form is available by contacting ITI at communications@trachoma.org. In that form, specific information is requested on the number of persons who received Zithromax® tablets or pediatric oral suspension during the quarter. It is important for programs to report on data at the district level, using the form provided by ITI, within 90 days after the distribution.

In addition to Zithromax® distributed during annual mass distribution campaigns, programs should include reporting on the distribution of Zithromax® in other ways, such as:

- Administered post trichiasis surgery
- During a prevalence survey
- Any other situations for which distribution of Pfizer-donated Zithromax® has been pre-approved

These different types of distribution of Zithromax® should be highlighted in the report to distinguish them from the doses distributed during MDA.

5.0 Annual Application Process

5.1 Overview

ITI has instituted an annual application process for new country applications as well as countries applying for additional rounds of Zithromax® treatments. This process is designed to assess a country's Zithromax® need over a five year horizon. The application requests information on up-to-date treatment distribution data, in-country inventory, and an update on prevalence data. The data collected in this process allows ITI to determine the long term Zithromax® needs in a particular country as well as evaluate the progress towards the elimination of blinding trachoma.

It is important to note that the Zithromax® donation is only approved when given in the context of the full SAFE strategy. Programs must ensure that the S,F, and E components are in place when applying for the Zithromax® donation.

5.2 Forecasting

Accurate and timely forecasts are critical to the timely provision of the Zithromax® donation that ITI receives from Pfizer Inc. Forecasts are requested from country programs more than 12 months in advance due to the planning, production, and shipping time necessary to meet the annual need for Zithromax®. A five year forecast is required by Pfizer to assess the manufacturing scale-up necessary to attain the elimination of blinding trachoma by the year 2020.

Delays in submission of the annual applications could impact the availability of Zithromax® to meet in-country requirements.

In general, the forecasting process begins in January with partner countries submitting the Zithromax® application and is concluded in October when the annual agreement is sent out detailing the Zithromax® support for the upcoming year. For example, applications submitted in January 2010 are requesting Zithromax® for the calendar year 2011.

The annual application requires each country to forecast at the district or implementation level. This allows the country to support their Zithromax® request based on the trachoma prevalence rates and population in the targeted district. Additionally, this level of detail allows all interested parties to follow the progression of treatment and progress toward eliminating blinding trachoma. Annual applications should be accompanied by expressions of support by implementing partners to the country program.

5.3 Annual Application Timeline

The annual application process encompasses four steps which are conducted at various times during the year. The four steps include:

1. Submission of the completed application by the Ministry of Health (MOH) to ITI
2. Application review at the annual forecasting meeting
3. Approval of a portion or entire application by the ITI Trachoma Expert Committee
4. Submission of ongoing distribution reports to ITI from the country program manager

Process	Timing	Actions
Submit	**January – March**	• ITI sends annual application to country program managers and partners • Country program managers return completed application with requested forecast and current inventory on hand
Review	**April – May**	• ITI reviews application and may request additional information from country program managers and partners • ITI compiles aggregate requested forecast • ITI shares requested forecast with Pfizer • Annual forecasting meeting held with country program managers and partners to review details of application
Approval	**June – October**	• ITI proposes country level allocations based on application and supporting evidence to TEC • Proposed country level allocations and new country applications are reviewed and approved by ITI's Trachoma Expert Committee. If an application is not approved a country will be notified by letter with a reason for denial. • ITI sends annual agreement to country program managers and partners indicating the Zithromax® support for the upcoming year
Report	**January – December**	• Countries report on treatments distributed on a quarterly basis • Countries report on remaining inventory annually • This process provides the needed details for the review and approval processes

5.4 Existing Country Applications

Applications from countries that are currently receiving Zithromax® must be received by February 15th for consideration of a donation for the following year.

The application requires the following information:

- Contact information
- Shipping information
- Current year treatment distribution detail at district level
- Updated population detail at district level, if available
- Three to five year forecast
- TT prevalence at district level
- Inventory on hand
- Most current TF and TI prevalence data at district level including year of survey
- Baseline prevalence TF and TI at district level
- Information on SAFE strategy component implementation

5.5 New Country Applications

ITI accepts applications from new countries seeking to receive the Zithromax® donation throughout the year, but only convenes the Trachoma Expert Committee twice per year to review submitted applications. The review typically takes place during the June and November time frames. If a county would like to have their application reviewed at the June meeting then their application should be submitted no later than March 31. If they would like to have it reviewed during the November meeting, the application should be submitted by September 30. A new country interested in submitting a formal application should send an email to communications@trachoma.org in order to obtain the most up to date application and further instructions. Currently, the TEC requires any new country to submit a 3 year national plan for trachoma elimination. A framework for such a plan is available through ITI. New countries should plan for implementation of the full SAFE strategy from the first year they receive Zithromax®.

5.6 Instructions on Completing the Annual Application

Detailed instructions for filling out the annual Zithromax® application are contained within the current version of the application. Since ITI is always looking to increase efficiency, the application may be updated each year so programs should be sure to obtain the most current version. Current versions of the application may be obtained by sending an email to communications@trachoma.org.

Only completed applications can be considered, so please take care to fill out the application in its entirety prior to submitting it to ITI, using the most up-to-date prevalence data available at the time.

5.7 ITI Trachoma Expert Committee (TEC) Review

After all the applications have been received and validated at the annual forecasting meeting, the ITI Trachoma Expert Committee will review each country's annual request and approve allocations based on each country's application and any additional supporting evidence. This review includes both current recipients of Zithromax® and new countries seeking to receive the donation. The TEC will only consider districts or communities that meet the WHO guidelines for Mass Drug Administration. (See section on Evaluation of Distribution.) Since approvals are granted at the district/implementation level unit, an application from a country may be approved in phases.

Countries that are currently receiving Zithromax® should note that TEC approval is required for distribution of Zithromax® in new districts/implementation units. If a program is considering an expansion to a previously untreated area or district, approval by the TEC is also required for that new area.

In general, the ITI Trachoma Expert Committee will make decisions on the annual applications in the June and November time frames.

Use of Zithromax® for unapproved uses or in areas not approved by the TEC will jeopardize the country's ability to receive drugs in the future.

5.8 Annual Zithromax® Agreement

Once the TEC has made its final approval of applications, ITI will generate country annual agreements. Once the agreement is complete, it will be sent to the Ministry of Health for review and signatures.

The annual agreement will include the quantity of Zithromax® that has been approved for the upcoming year. ITI will also detail the quantities to be distributed within each approved district. Questions on districts that have not been approved for distribution of Zithromax® should be directed to ITI. If a country has not been approved for a donation, a letter will be sent to notify the country and explain the reasons for denial.

Since there is a significant space of time between the initial submission of the application and the approval process, there may be a need for ITI to request an updated in-country inventory report from applicants. The total amount of viable Zithromax® inventory in-country will be deducted from the total approved quantities.

In general, the annual agreement will be sent out to the Ministry of Health during the month of October. ITI will require original signed copies of the annual agreement from the MOH.

5.9 Reporting

As part of the annual agreement for the Zithromax® donation, national programs are required to report on a quarterly basis to ITI on the distribution of Zithromax.® (See Annex for an example of the quarterly report.)

6.0 Supply Chain

6.1 Preparing for Shipment

The stages involved in the shipment preparation are detailed in the following section.

6.1 REVIEW OF CONTACT TREE

A contact tree is a document sent to the country program manager by ITI that provides ITI with the contact information (names and addresses) of the person(s) responsible for receiving the shipment of Zithromax® in a country program. The contact tree form is sent to the country program before the Zithromax® shipment. The name(s) and the address(es) in the contact tree will appear in all the subsequent shipping documents. Once the contact tree is reviewed and necessary changes (if any) are made by the country program, it should be sent back to ITI. It is the responsibility of the country program manager to review the contact tree before planning a shipment of Zithromax® and to immediately communicate any changes to ITI.

6.1.2 CERTIFICATION OF DONATION (COD) AND PRO FORMA INVOICE

Once the contact tree has been confirmed, ITI will pass on the contact tree to Pfizer staff to verify shipment. Then, they will generate both the COD and pro forma invoice for the shipment and send it back to ITI. Generally, a COD will contain the following information:

Children and men carrying trachoma MDA campaign supplies through a swamp in Sudan.

1. The amount of Zithromax® to be donated and shipped to the country program
2. Specifies Zithromax® as 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. Designates Zithromax® donation for use in trachoma programming

Generally, a pro forma invoice will contain the following information:

1. Name and address of organization to which the donation will be shipped
2. Name and address of the organization to which the product has been donated

3. Brief product description

4. The amount of Zithromax® to be donated (This quantity should match the quantity in the Certificate of Donation)

6.1.3 PRE-SHIPMENT DOCUMENT CHECKING

ITI will send an electronic copy of the Certificate of Donation (COD) and the pro forma invoice to the country program manager and other parties responsible for receiving the Zithromax® shipment. After receiving the documents, the country program manager must send a copy to its clearing agent to prepare for the shipment.

6.1.4 "GREEN LIGHT" FOR SHIPMENT

A "green light" is essentially a confirmation message from the country program manager to ITI stating that the country is ready to receive the Zithromax® shipment. The country program manager must confirm the following preparations have been completed before sending a green light note:

Green Light Check List		
Communication	Are the customs agents aware of the shipment and the quantities of the shipment?	Yes / No
Customs Clearance Waiver	Has the customs clearance duty waiver been prepared?	Yes / No
Customs Duty	Is the money ready to pay for duty for the inbound shipment?	Yes / No
Warehouse Space	Does the central medical store have space to receive the shipment?	Yes / No
Distribution	Is the country prepared to distribute the Zithromax®?	Yes / No

The county program manager must understand that once a "green light" note is sent, further changes will not be possible in the documents or the physical shipment!

If any of these conditions have not yet been satisfied, the country program manager should contact ITI immediately to notify the changes required. Once all the conditions have been met, the country program manager will send the green light note.

6.1.5 FINAL SHIPPING DOCUMENTS FROM ITI

Once the green light has been received, Pfizer will prepare the final shipping documents (Certification of Analysis, Airway Bill, Packing List, and Certification of Origin — as applicable). If any additional documents are required by the country program for customs clearance, ITI should be notified immediately. Once Pfizer prepares the documents, they will be sent to ITI and then to the country program manager by email. Original documents can be also sent via courier if they are required for customs clearance.

6.1.6 FINAL ARRANGEMENTS FOR THE IN-BOUND SHIPMENT

Once all the final documents have been received, the clearing agent should be notified of the date of the shipment and expected date of arrival.

6.1.7 CUSTOMS CLEARANCE

Once the Zithromax® has arrived in the country, the country program manager should work closely with their customs clearing agent for timely clearance of the shipment. The time required to complete customs clearance can vary from country to country 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:

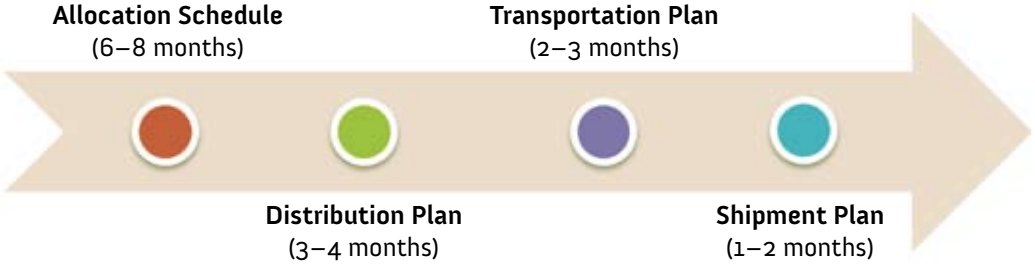
- Demurrage charges for late clearance
- Physical damage/loss of the drug
- Changes in the drugs due to poor storage (e.g. high temperature)

6.1.8 CONFIRMATION

When the shipment has been cleared from customs, a confirmation of the total physical quantity of bottles of Zithromax® (both tablets and POS) received in good condition will be necessary. A confirmation document (see the Annex for Receipt Confirmation Form) should be sent to ITI within 7 days of the arrival of the shipment in country. Ideally, it should be sent after a physical inventory count and inspection of the products received (see the section on physical inventory). Any damage/loss that occurred in the shipment process should also be noted, with the exact amount in the confirmation document.

6.2 Distribution and Transportation Planning

A detailed Distribution and Transportation Plan should be drawn up to determine the quantity of Zithromax® that should be sent to regional/district storage facilities based upon the annual country agreement approved district allocations. It should be created and agreed upon by key implementing partners at least three to four months prior to the beginning of distribution. The following schematic diagram shows the major steps:



Planning Steps and Timeline

MDA campaign supplies en-route to a distribution site in Sudan.

6.3 Allocation Schedule

- An Allocation Schedule (see Annex for template) gives an estimate of the quantity of Zithromax® required to treat the target population of the country by district.
- Zithromax® can only be allocated to districts that have been approved by the ITI Trachoma Expert Committee. Allocating drug to non-approved districts is considered a violation of the annual agreement and will jeopardize a country's potential to receive Zithromax® in the future.
- Based on the target population in each of the localities, estimates of the number of cases of tablets and POS required are determined by the following formulae.
- It is generally estimated that 80% of a population is above 5 years of age and is thus eligible for tablets. Similarly, 18% are estimated to take POS. The remaining 2% should be eligible to receive tetracycline eye ointment.
- In general, a treatment of Zithromax® consists of an average of 3 tablets or 10ml of POS.

$$\text{Gross tablets required (bottles)} = \frac{\text{Total population} \times 0.8 \times 3}{30^{*}}$$

$$\text{Gross POS required (bottles)} = \frac{\text{Total population} \times 0.18 \times 10}{30^{*}}$$

$$\text{Tablets required (cartons)} = \frac{\text{Gross tablets required (bottles)} - \text{on hand inventory (bottles)}}{48^{**}}$$

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

** Numbers based on current size of the bottle.* *** Numbers based on current numbers of bottles per carton.*

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

Example: For a population of 100,000 persons

Current inventory: Tablets = 2,000 bottles; POS = 2,500 bottles

$$\text{Gross tablets required (bottles)} = \frac{100{,}000 \times 0.8 \times 3}{30} = 8{,}000$$

$$\text{Gross POS required (bottles)} = \frac{100{,}000 \times 0.18 \times 10}{30^{*}} = 6{,}000$$

$$\text{Tablets required (cartons)} = \frac{8{,}000 - 2{,}000}{48} = 125$$

$$\text{POS required (cartons)} = \frac{6{,}000 - 2{,}500}{48} = 73$$

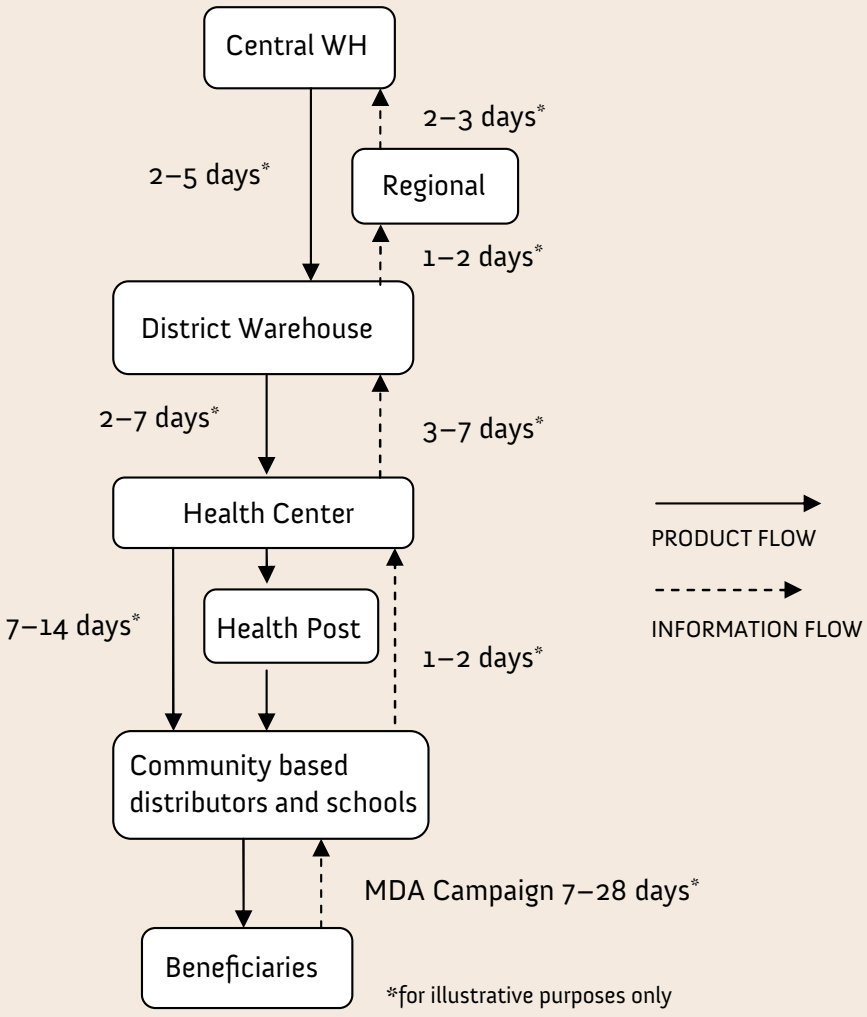
7.0 Distribution and Transportation Plan

7.1 Distribution Plan

- Review the allocation schedule for distribution and check stock in the central warehouse to ensure sufficient supply for distribution.
- Schedule a distribution plan based on the field distribution dates of the districts. Record both the earliest and latest delivery time for every district.
- All the facilities receiving Zithromax® must ensure sufficient storage capacity for the product by the earliest delivery date.
- All the districts must receive the Zithromax® supply in the full quantity required for the MDA at least two to three weeks before the distribution begins.

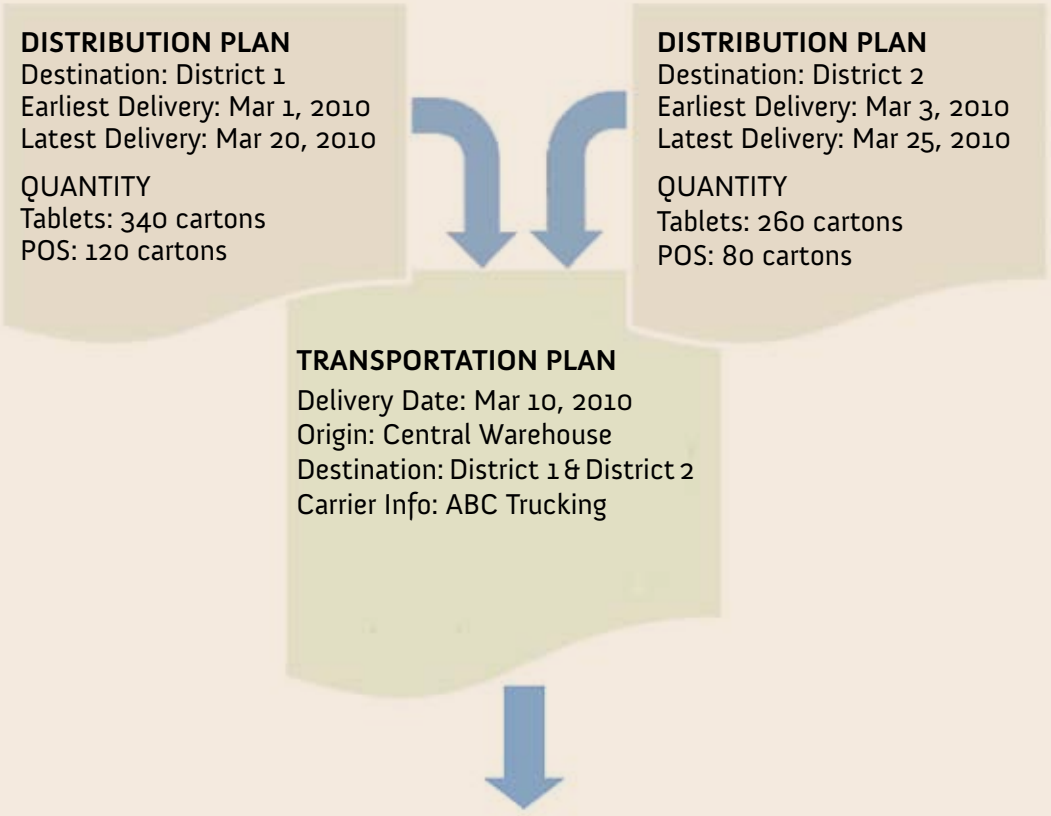
7.2 Transportation & Shipment Plan

- After the distribution plan is completed, possible transportation modes, routes and dates should be fixed for all the shipments. If the country program manager does not have direct control over the shipment dates and transportation mode, coordination will be necessary with the appropriate local, regional, or national authorities to ensure timely shipment of Zithromax® before the distribution begins.



Physical Product and Information Flow

- If a district requires less than a full truckload of Zithromax®, its delivery should be clustered together 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 going to the same destination from the central warehouse.
- If a third party transportation provider is used, a contract should be signed by the MOH to protect against damage/loss of the product during transportation.
- After the dates are confirmed by the transportation provider, a detailed shipment plan should be made, with the exact date, 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.



SHIPMENT PLAN
(from Central Warehouse)

Serial no.	Date	Destination	Quantity (Tablets) in cartons	Quantity (POS) in cartons	Carrier name/ Phone number
1	3/10/10	District 1	340	120	ABC Trucking Phone number: xxxx
2	3/10/10	District 2	260	80	

Illustrative Example of Logistics Planning

7.2.1 PRODUCT SPECIFICATIONS

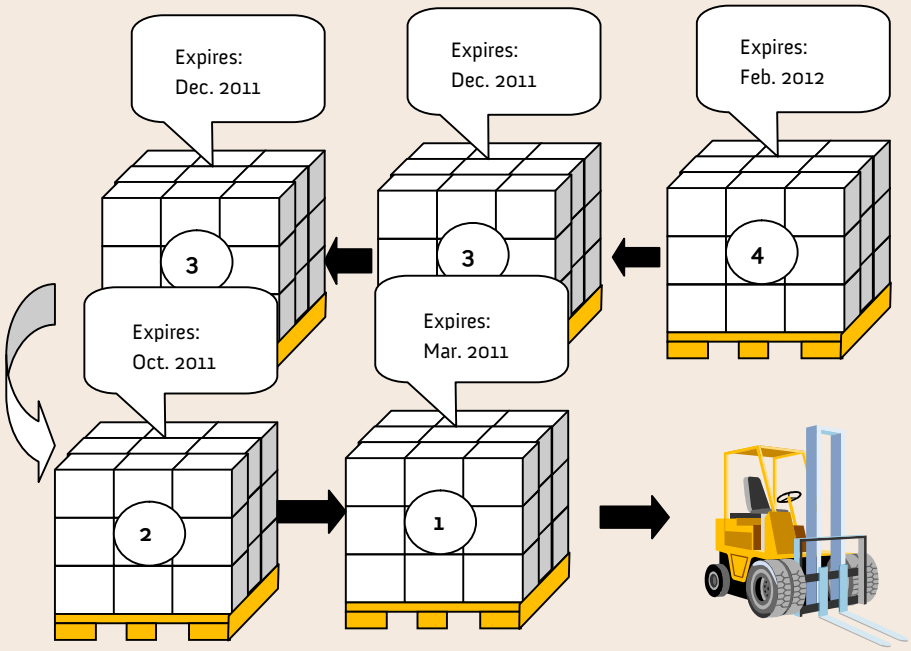
Product Specifications	30 ml bottles of Pediatric Oral Suspension (POS)	30 count bottle of tablets
Average treatment per bottle	3	10
Number of bottles per carton	48	48
Number of cartons per pallet	24	70
Case weight (kg)	5.1	1.9
Pallet weight (kg)	123	133
Carton dimensions (L x l x H) cm	37.5 X 29 X 25	31.8 X 27.3 X 7.8
Pallet dimensions (L x l x H) cm	80 X 120 X 120	80 X 120 X 109.2

7.3 Managing the Zithromax® Inventory

7.3.1 RECEIVING AND STORING ZITHROMAX®

- Ensure that there is sufficient storage space.
- Prepare and clean the areas used for receiving and storing the cartons.
- Inspect the cartons for any damaged or expired product.
- If the drugs are damaged or expired, follow the procedure described in the section (Managing Damaged or Expired Drugs).
- Update the stock card immediately after receiving the cartons (see details in the Record Keeping section).

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



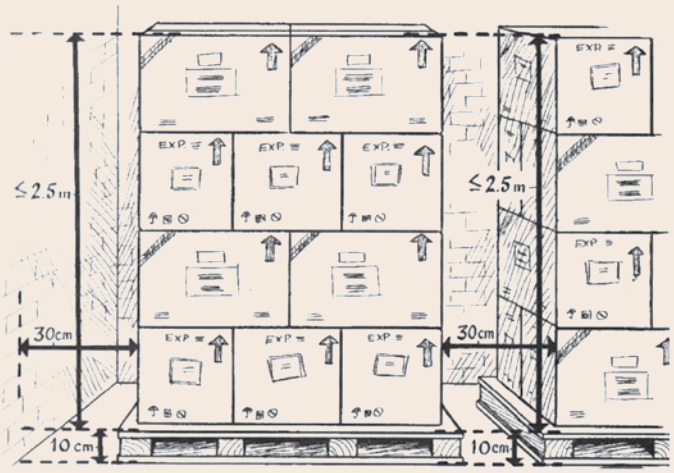
First-Expiry-First-Out (FEFO) policy

Zithromax® absolutely cannot be distributed after its expiration date!

7.4 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 only to designated staff. Also limit the number of keys to the storage facility and keep a list of the people who have keys.**



Storage Guideline

Source: Guidelines for the storage of Essential medicines – (DELIVER)

- As a general rule, all usable drugs should be stored:
  - At least 10 cm (4 inches) off the floor
  - At least 30 cm (1 ft) away from the walls or other stack
  - No more than 2.5 m (8 ft) high
- Store the Zithromax® Tablets and POS in separate stacks.
- Storage of Zithromax® at all levels (central medical stores, regional warehouses, district warehouses, local health center stores, etc.) should be stacked in a manner such that the Zithromax® stock with the nearest date of expiry is closest to the door, and can be gathered with ease. The remaining Zithromax® stock should be organized by the descending order of nearest expiry dates (i.e., stock with the farthest expiry date shall be farthest away from the door).

- After each issue/receipt of the drug, all the stacks should be re-arranged to maintain the First-Expiry-First-Out (FEFO) order as described above.
- Stack damaged/expired drugs in a separate place with appropriate caution marking **"DO NOT USE — Damaged/Expired products"** (See section on managing damaged/expired drugs)
- Store Zithromax® in a shaded facility where the temperature is below 30° Celsius.
- Use shades/curtains on the windows if drugs are exposed to direct sunlight.
- Arrange the cartons so that the identification labels and expiry dates are visible.

7.5 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 central storage facility: only break one pallet at a time.
- For district level storage: Always issue in full cartons, if possible. Do not break the carton to issue single bottles unless it is distributed to community distributors.
- At any time, only one carton should be opened to issue bottles at the community level.
- Update the stock card immediately after issuing drugs from storage (see details in the Record Keeping section).

Properly stacked cartons would have all expiry date labels facing forward.

7.6 Record Keeping

Record keeping is the most essential part of inventory management. Zithromax® inventory is accounted for on two important forms:

- Stock cards
- Transfer forms

These two forms will keep track of all the product movements in the distribution channel of Zithromax®. All the storage facilities in the distribution channel should use these two forms to record updated stock and the history of all transactions or adjustments. (i.e., product receiving, issuing, distribution, and physical inventory reconciliation)

7.6.1 STOCK CARD (SEE ANNEX FOR SAMPLE):

- Stock cards record all the stock received, issued, and adjustments done in a storage location.
- Separate stock cards should be used for Zithromax® tablets and POS.
- Every time a shipment is received or issued, it should be entered into 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 5 years at each location.

7.6.2 TRANSFER FORM (SEE ANNEX FOR SAMPLE):

- 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 another 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.
- Community-directed drug distribution teams can also use the same form when receiving Zithromax.® After the distribution, they should return the empty and unused bottles and complete the second section of the form. In this case, only the unused quantities should be added to the stock and used and empty bottles should be shown as distribution in the adjustment section with a note as "used in distribution".
- Records of all the transfer forms should be kept for at least 5 years.

7.7 Managing Close-Dated Drugs

Like all other medicines, Zithromax® has a specific expiry date. **Under no circumstances should expired drugs be distributed.** Zithromax® has a shelf life of 36 months from the date of manufacture. 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.

Accurately completing the post MDA checklist and sending it to the country program manager in a timely fashion ensures effective administration of product with less than 13 months of shelf-life remaining.

Time to Expire	Action Guideline Before the Distribution	Action Guideline During and After the Distribution
Less than 13 months **Category A** *Urgent action required*	• Separate them from other inventories • Use all the products from this lot first in the distribution	• Look for opportunities to use the drugs in other districts/areas where the distribution has not yet started or finished. • If no such use is possible, report the quantity immediately to the country program coordinator. • If a large quantity of such inventory is present in the country, report it to ITI immediately.
13 months to 24 months **Category B** *Inventory Alert*	• Separate them from other inventories. • Use the products of this category after using category A products.	• Make sure to report such inventory of drugs clearly in the post MDA inventory report
25 months and more **Category C** *Normal inventory*	• No action necessary. Just follow FEFO policy	• Complete the post MDA checklist in timely fashion.

How to Manage Close-Dated Drugs

If more than 1,000 bottles of Zithromax® with an expiry date of less than 13 months are present in a country, it should be immediately reported to ITI.

7.8 Managing Damaged/Expired Drugs

Damaged/expired drugs should NOT be administered under any circumstances. If the product is found in any of the following four conditions, then it should be disposed of according to the six step guidelines below:

1. Any Zithromax® tablets or POS that have expired
2. Damaged bottles of Zithromax® (e.g., punctured or leaking bottle)
3. All open bottles of reconstituted Zithromax® POS bottles remaining after the completion of the MDA campaign
4. Any Zithromax® bottle without any expiry date or illegible label

Damaged or expired drugs should immediately be reported to the country program manager. The disposal of the unusable drugs should be done in the following manner:

Step 1	Separate the damaged/expired drug from other usable inventories
Step 2	Attach proper cautionary sign or label
Step 3	Inform country program manager 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 the guideline

7.9 Zithromax® Disposal Methods

One of the following disposal methods should be used to dispose of the damaged/expired drugs based on the preferred method.

Priority scale	Disposal method	Methods
First	**Country medicine disposal guideline/protocol**	• Find the Ministry of Health 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**[1]	• 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

High temperature incineration.

7.10 Managing Empty Bottles

All the empty bottles after the distribution should be collected from the community distribution teams for disposal.

After the bottles are collected, they are disposed of according to the country guideline. In absence of the guideline, there are three methods to dispose of plastic bottles in descending preference priority:

Defaced battles

Bottles must be defaced using a black, permanent, and waterproof marker by placing "X" marks on all sides of the bottles.

Priority scale	Actions	Guidelines
First	**Reuse**	The bottles can be only reused after they are properly cleaned and defaced using a permanent marker. The Zithromax® label is pressure sensitive and cannot easily be peeled off.
Second	**Recycle**	If the bottles are not reused then they can be sent to a plastic recycling facility if available.
Third	**Bury**	All the empty bottles should be buried in a closed pit or sent to landfills.

How to Manage Empty Bottles Based Priority

Burying empty Zithromax® bottles in a closed pit in Mauritania.

A team of two people conduct a physical inventory in Sudan.

7.11 Physical Inventory

The purpose of a physical inventory is to reconcile the on hand inventory on the stock card and the physical inventory at the storage facility. When conducting a physical inventory, all products in storage should be counted. No transactions should take place during the counting process. The physical inventory process should be finished as quickly as possible in order to resume normal operation in the storage facility. The following steps should be followed to conduct a complete physical inventory for Zithromax.®

Phoning the districts for a mid-year inventory update is sufficient, but should not be used in lieu of the annual physical inventory.

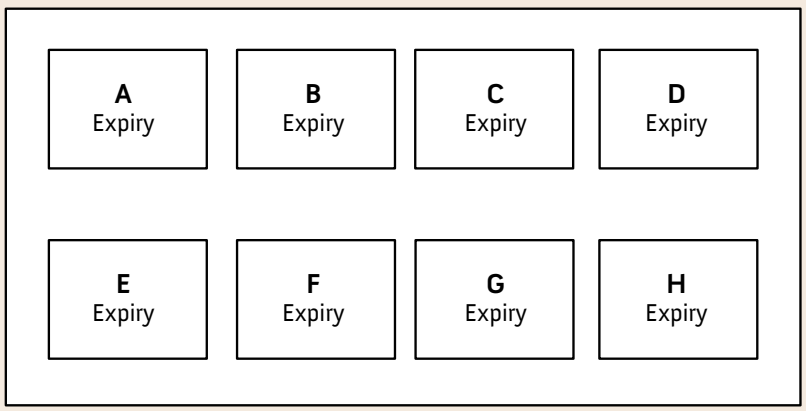
A physical inventory should be conducted at the end of each MDA campaign.

1. Plan:

- Plan a specific date and time for the physical inventory.
- Identify the persons who shall 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.

2. Organize the storage facility:

- Arrange the product (both tablets and POS) separately and by expiry date.
- All the partially used bottles should be kept separate from the unopened bottles.
- Separate the damaged and expired drug from other usable inventory.
- For ease in counting, count bottles according to their expiry date group.



Sample floor layout: a storage facility showing stock separation according to expiry date.

3. 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 in the Annex.)
- Count the number of bottles per expiry date group.
- For partially used bottles of tablets, estimate the quantity based on volume of the original package. For example, if a new bottle of Zithromax® tablet contains 30 tablets, then estimate the ½ full bottle with 15 tablets. Any open Zithromax® POS bottle should not be in the inventory, it should be disposed of immediately after the MDA campaign.

4. Update the stock card:

- Once counting is finished, reconcile the total bottles counted with the inventory on hand. For any difference, add or subtract it from the stock card under Loss/Adjustment. Clearly mention the date, quantity difference, and write "Physical Inventory" with a different color ink.
- Example:

STOCK CARD (Zithromax® Tablets)							
Storage Facility Name:				Bottles			
Date	Transfer form serial no.	Origin/ Destination	Quantity Received	Quantity Issued	Losses/ Adjustments	Quantity on hand	Signature of the store in-charge
15 Dec 10	234	Central Warehouse	340	0	0	740	
15 Dec 10	**NA**	**PHYSICAL**	**INVENTORY**	**——**	**(50)**	**690**	

5. Take actions:

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

7.12 SUPPLY CHAIN AUDITS

Supply chain audits are routinely conducted for all countries preparing to receive the Zithromax® donation for the first time. The overall purpose of the supply chain audit is to collect key information on the supply chain to identify gaps and opportunities. The initial supply chain audits specifically assess a country's ability to successfully clear customs, store, and distribute Zithromax®. If issues are identified then they must be addressed prior to the country's receipt of a large shipment. In addition to the initial supply chain audit, subsequent audits may be conducted on a periodic basis to review the current status of the supply chain. If selected for a periodic supply chain audit, ITI will be in contact with the country program manager. The country program manager will be asked to assist in preparation and actively participate in the in-country audit.

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 audit: (Review the Zithromax® Supply Chain Audit form in the Annex that is to be used during a supply chain audit.)

- Drug customs clearance
- Forecasting methodology
- Inventory control
- Supply chain security
- Storage facility conditions
- Transportation and distribution
- Practice of First-Expiry-First-Out methodology

8.0 Importance of Evaluating Distribution

8.1 Evaluation of Distribution

It is important for national programs to evaluate their efforts toward eliminating blinding trachoma through implementation of the SAFE strategy, including the effect of mass antibiotic distribution. The best strategy for evaluating the effect of MDA is through prevalence surveys as described in the World Health Organization manual "Trachoma Control: A Guide for Programme Managers." This manual recommends the following (page 21):

If the baseline district prevalence of TF in 1-9 year old children is 10% or greater, antibiotic treatment of all residents should be undertaken annually for 3 years. After these three treatments, a repeat district survey should be carried out. If the district prevalence of TF in 1-9 year old children is still 10% or greater, annual mass treatment should be continued. If the prevalence is less than 10%, surveys should be conducted to determine the prevalence at community level. Then, in communities in which the prevalence is less than

5%, treatment can be stopped; and in communities in which the prevalence is 5% or greater, annual treatment should continue until such time as it falls below 5%.

If the baseline district prevalence of TF in 1-9 year old children is less than 10%, the prevalence should be determined at community level.

- *In communities in which the baseline prevalence is 10% or greater, mass treatment should be undertaken annually for 3 years. A repeat survey should be carried out after 3 years. Then, in communities in which the prevalence has fallen below 5%, treatment can be stopped. In communities in which the prevalence is 5% or above, annual treatment should continue until such time as it falls below 5%.*
- *In communities in which the baseline prevalence is 5% or greater but less than 10%, F and E interventions should be implemented (without antibiotic treatment) for 3 years. A repeat survey should be carried out after 3 years. If the community-level prevalence has fallen below 5%, active trachoma control interventions can be discontinued. If the community-level prevalence is 5-10%, F and E interventions should be continued for another 3 years.*
- *In communities in which the baseline prevalence is less than 5%, implementation of the A, F, and E components of SAFE is not a priority.*

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.

Glossary

CDD	Community-Directed Distributor
CO	Corneal Opacity
COD	Certificate of Donation
ETA	Estimated Time of Arrival
FEFO	First-Expiry, First-Out
GET2020	Alliance for the Global Elimination of blinding Trachoma by the year 2020
HQ	Headquarters
ITI	International Trachoma Initiative
LMIS	Logistics Management Information System
MALTRA	Integrated Malaria and Trachoma Control Project
MDA	Mass Drug Administration
MOH	Ministry of Health
NGO	Non-Governmental Organization
NTD	Neglected Tropical Disease
POS	Pediatric Oral Suspension
SAE	Serious Adverse Experience
SAFE	Surgery, Antibiotics, Face-washing, Environmental improvement
SDP	Service Delivery Point
TEC	Trachoma Expert Committee
TEO	Tetracycline Eye Ointment
TF	Trachoma Inflammation — Follicular
TFGH	Task Force for Global Health
TI	Trachoma Inflammation — Intense
TS	Trachomatous Scarring
TT	Trachomatous Trichiasis
WHO	World Health Organization

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World Health Organization (1999) Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis (in countries where onchocerciasis is co-endemic) A Guideline for Programme Managers. Geneva: WHO. WHO/CDS/CPE/CEE/2000.16.

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WHO, UNICEF, & USAID (2002) Communication for polio eradication and routine immunizations: Checklists and Easy Reference Guides. Geneva: WHO. WHO/POLIO/02.06.

Annex

Census and Treatment Form

Community:_____ Distribution Point:_____ Page_____ of _____

Date of Census:_____ Head of Household:_____ Census Prepared by:_____

No.	Name	Sex F/M	Age	Treatment: 20____			Treatment: 20____			Treatment: 20____			Comments
				TABS[1]	POS[2]	TEO[3]	TABS[1]	POS[2]	TEO[3]	TABS[1]	POS[2]	TEO[3]	
		Totals this page:											

Place an "X" in the box for type of treatment received.

1. Zithromax® Tablets; 2. Zithromax® Pediatric Oral Suspension; 3. Tetracycline Eye Ointment

Serious Adverse Experience Report

Serious Adverse Experience Report

A **serious adverse experience (SAE)** is defined as an adverse experience following treatment with a drug that results in any of the following:

- **death**
- **life-threatening condition**
- **in-patient hospitalization or prolongation of an existing hospitalization**
- **persistent or significant disability/incapacity**
- **congenital anomaly or birth defect**
- **cancer**
- **overdose (accidental or intentional)**

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in the definition above: such events should also be reported.

COMPLETE THIS FORM ONLY IF THE ADVERSE EXPERIENCE MEETS THE ABOVE CRITERIA
and
send within 48 hours to:

International Trachoma Initiative
325 Swanton Way
Decatur, GA 30030
USA

TEL: +1-404-371-0466 / +1-404-592-1478

FAX: +1-404-371-1138

E-mail: DHaddad@taskforce.org and LRotondo@taskforce.org

Serious Adverse Experience (SAE) Report

Distribution of Zithromax® for trachoma control

Country: _____	**Date of Report:** __/__/____ (Day/Month/Year)

1. Source of Report (reporter(s) of the data in this report*	
_____ **Name** (First/Middle/Last)	
_____ **Title**	
_____ **Organization**	
_____ **Address**	
_____ **Telephone Number**	_____ **Fax Number**

*This report must be completed by a licensed physician

2. Patient Information		
_____ **Name** (First/Middle/Last)	_____ ***Age*** (in years)	_____ ***Sex*** (M/F)
_____ ***Village***	_____ ***District***	_____ ***Province/Region***

3. Pre-existing Conditions	
Health Status before administration of Zithromax® (including any central nervous system disability):	
Illnesses/infections, known or suspected (e.g.,malaria) ⇒	_____

Other medications being taken (currently or recently) ⇒	_____
Is patient pregnant? ☐ Yes ☐ No ☐ Unknown	
Alcohol*:* a) Consumption of alcohol within 24 hours of taking Zithromax® ⇒	_____
b) History of Chronic Alcoholism ⇒	_____

4. Information on Recent Zithromax® Administration			
Date of Zithromax® administration prior to onset of SAE (Day/Month/Year): _____			
Source of MDA: ☐ Community treatment program ☐ Clinic or physician treatment ☐ Other method	***Dose of Zithromax® administered*** (no. of tablets/ml)	***Patient's height*** (cm)	***Patient's weight*** (kg)
	☐ _____tablets ☐ _____ml	_____	_____
Was this a first administration with Zithromax®? ☐ Yes ☐ No ☐ Unknown If "No", use the space below to give dates and circumstances of past treatment(s):			

5. Description of the Serious Adverse Experience (SAE)	
_____ ***Date of onset*** (Day/Month/Year)	_____hours OR _____ days ***How long after Zithromax® was taken did the SAE occur?***
Use the space below to describe clinical signs and symptoms ***Were there signs of acute alcohol intoxication on initial examination?*** ☐Yes ☐ No ☐ Unknown	
Laboratory results (attach all relevant test reports and data)	**Dates of tests** (Day/Month/Year)

Case management, clinical course, drugs used *(e.g. Hospitalization – provide date of admission and summarize the reason for admission)*:

a) Hospitalization: ☐ Yes ☐ No

If "Yes", indicate: Date of admission (Day/Month/Year): _____

Date of discharge (Day/Month/Year) : _____

(Attach any relevant reports)

b) Use the space below to describe treatments administered:

6. Condition/Outcome at time of last observation		
Full recovery: ☐ Yes ☐ No ☐ Unknown If "No" or "Unknown", please explain:		
Ongoing illness: ☐ Yes ☐ No ☐ Unknown If "Yes", please explain:		
Persistent/Significant Disability/Incapacity: ☐ Yes ☐ No ☐ Unknown If "Yes", describe:		
Death: ☐Yes ☐ No	***Date of death*** (day/month/year) _____	***Cause of death*** _____
In fatal cases please provide circumstances at the time of death in detail below. Report any autopsy findings made including tissues taken for histopathology and any additional studies done or requested (use additional pages necessary to complete your answers):		
Presumptive diagnosis:		

7. Conclusions
Do you think the administration of Zithromax® for trachoma control was a causative possible factor in this SAE?   ☐ Yes ☐ No ☐ Not sure   If "Yes", explain in the space below: If "No", or "Not sure", what do you believe was the cause of the event?

Please send this report to the following:

International Trachoma Initiative
325 Swanton Way
Decatur, GA 30030
USA

TEL: +1-404-371-0466 / +1-404-592-1478
FAX: +1-404-371-1138
E-mail: DHaddad@taskforce.org and
LRotondo@taskforce.org

District Level Distribution Summary Report

Region:_____ District:_____ Report Date:_____

No.	Distribution Point	Number of Persons who received Zithromax® tablets		Number of Persons who received Zithromax® POS		Number of Persons who received TEO[1]	
		Total Males Treated	Total Females Treated	Total Males Treated	Total Females Treated	Total Males Treated	Total Females Treated
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
Total							

1 Tetracycline Eye Ointment

International Trachoma Initiative

Sample Quarterly Report to the International Trachoma Initiative from National Programs

	Region	District	District Population	Number of Persons who received Zithromax ® Tablets					Number of Persons who received Zithromax ® Pediatric Oral Suspension					Number of Persons who received Tetracycline				
				Q1	Q2	Q3	Q4	Total	Q1	Q2	Q3	Q4	Total	Q1	Q2	Q3	Q4	Total
1								0					0					0
2								0					0					0
3								0					0					0
4								0					0					0
5								0					0					0
6								0					0					0
7								0					0					0
8								0					0					0
9								0					0					0
10								0					0					0
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15								0					0					0
16								0					0					0
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21								0					0					0
22								0					0					0
23								0					0					0
24								0					0					0
25								0					0					0
26								0					0					0
27								0					0					0
28								0					0					0
29								0					0					0
30								0					0					0
				Total Persons Received Zithromax ® (POS and Tablets)									0	Total Zithromax ® and TEO				0

Quarterly Reports are due to ITI based on the following schedule:
- Q1: data from January through March are due May 15
- Q2: data from April through June are due August 15
- Q3: data from July through September are due November 15
- Q4: data from October through December are due February 15

POS: Pediatric Oral Suspension
TEO: Tetracycline Eye Ointment

Certificate of Donation

Date

Dr. Danny Haddad
Program Director
Global Health Solution, Inc
325 Swanton Way
Decatur, GA 30030

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

Dear **Dr. Haddad:**

Pfizer Inc. is pleased to collaborate with (**NGO Name)**, the International Trachoma Initiative 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 **(NGO)**:

- **(Quantity Bottles)** bottles, 1200mg of Zithromax® (azithromycin) pediatric oral suspension (cherry flavor), at 48 bottles per case **(Quantity of full cases)**, with 288 plastic dosing cups per case; and

- **(Quantity Bottles)** bottles, 30-count, of Zithromax® (azithromycin) 250mg tablets (red-coated), at 48 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 Pharmaceutical Supplies and Logistics Department (PSLD) will assist with clearance, transport, and central storage. If you have questions, please work with Laurence Ligot (Laurence.Ligot@pfizer.com).

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

Sincerely,

Rachel Seligson
Sr. Manager, International Philanthropy Programs
Pfizer, Inc.

Pro Forma Invoice

PFIZER H.C.P. CORPORATION
CENTRAL & EASTERN EUROPE REGION
235 EAST 42nd STREET
NEW YORK 10017
UNITED STATES OF AMERICA
FR 55508086758

1/12/09	ETH 00015 000	
Our Reference	Order N°.	Customer N°.
	QF S 5355	8013 A74

Invoice Date	Invoice N°.	Page
17/02/10	QF00002913	1
	INVOICE	IN

Ship To
FEDERAL MINISTRY OF HEALTH C/O
PHARMACEUTICAL FUND & SUPPLY AGENCY

Sold To
GLOBAL HEALTH SOLUTIONS I
GLOBAL HEALTH SOLUTIONS,INC
325 SWANTON AVENUE
GA 30322 DECATUR
UNITED STATES OF AMERICA

Marks
TRACHOMA DONATION

Ship From
Transport AIR TRANSPORT
Import Licence
Terms of sale

Terms of Payments NO PAYMENT

Destination ETHIOPIA

Item	Product Description	Sales Unit	Unit Price	Quantity	Amount
001	ZITHROMAX POS 1200MG	BTL	5,700	250032,000	1.425.182,40 USD

. . FOR CUSTOMS ONLY . . .

DONATION

CODE 0656933 LOCAL CODE 031609 CUST.TRF. 3004200000
ISS-NBR. ETH 00015 00

LOT 96420101 QTY 309,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 113820 001
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

LOT 96420701 QTY 640,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 114122 001
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

LOT 96421401 QTY 636,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 111426 001
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

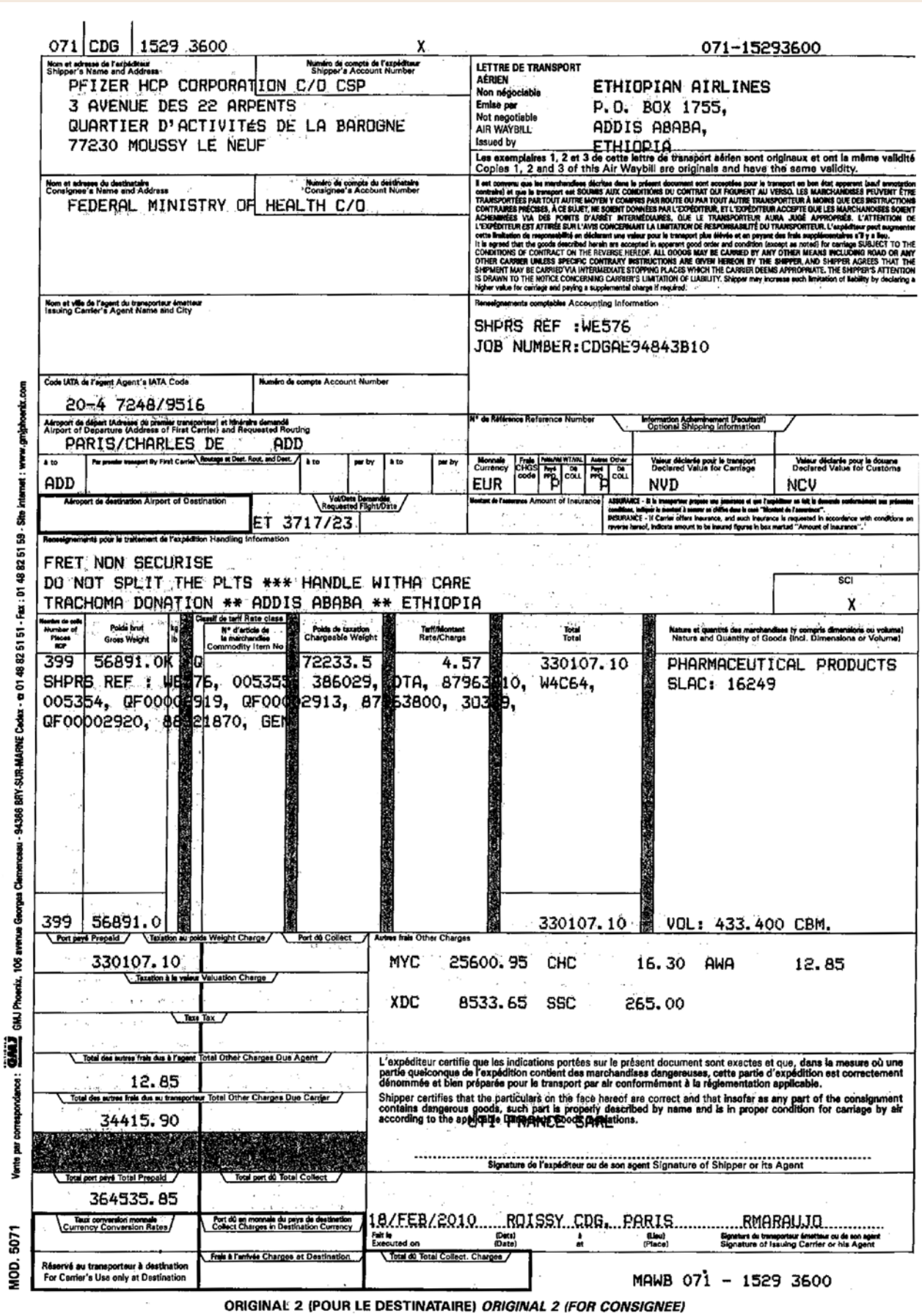
LOT 96421701 QTY 38,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 114281 004
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

LOT 96422301 QTY 630,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 114281 002
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

LOT 96422401 QTY 428,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE
MFD 2009/09 EXP. 2012/09 P.O. D 114281 003
ORIGIN 8221 I ITALY
PROVENANCE 8221 I ITALY

LOT 96422501 QTY 625,000 CSE
CLEARED CUSTOMS DOC.NR. : NONE CUSTOMS STATUS FREE

Air Waybill



071 | CDG | 1529 3600 X 071-15293600

Nom et adresse de l'expéditeur Shipper's Name and Address
PFIZER HCP CORPORATION C/O CSP
3 AVENUE DES 22 ARPENTS
QUARTIER D'ACTIVITéS DE LA BARONGNE
77230 MOUSSY LE NEUF

Numéro de compte de l'expéditeur Shipper's Account Number

LETTRE DE TRANSPORT AÉRIEN Non négociable / Not negotiable AIR WAYBILL
Emise par / Issued by: ETHIOPIAN AIRLINES, P.O. BOX 1755, ADDIS ABABA, ETHIOPIA

Les exemplaires 1, 2 et 3 de cette lettre de transport aérien sont originaux et ont la même validité
Copies 1, 2 and 3 of this Air Waybill are originals and have the same validity.

Nom et adresse du destinataire Consignee's Name and Address
FEDERAL MINISTRY OF HEALTH C/O

Numéro de compte du destinataire Consignee's Account Number

Il est convenu que les marchandises décrites dans le présent document sont acceptées pour le transport en bon état apparent (sauf annotation contraire) et que le transport est SOUMIS AUX CONDITIONS DU CONTRAT QUI FIGURENT AU VERSO. LES MARCHANDISES PEUVENT ÊTRE TRANSPORTÉES PAR TOUT AUTRE MOYEN Y COMPRIS PAR ROUTE OU PAR TOUT AUTRE TRANSPORTEUR À MOINS QUE DES INSTRUCTIONS CONTRAIRES PRÉCISES, À CE SUJET, NE SOIENT DONNÉES PAR L'EXPÉDITEUR, ET L'EXPÉDITEUR ACCEPTE QUE LES MARCHANDISES SOIENT ACHEMINÉES VIA DES POINTS D'ARRÊT INTERMÉDIAIRES, QUE LE TRANSPORTEUR AURA JUGÉ APPROPRIÉS. L'ATTENTION DE L'EXPÉDITEUR EST ATTIRÉE SUR L'AVIS CONCERNANT LA LIMITATION DE RESPONSABILITÉ DU TRANSPORTEUR. L'expéditeur peut augmenter cette limitation de responsabilité en déclarant une valeur pour le transport plus élevée et en payant des frais supplémentaires s'il y a lieu.
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.

Nom et ville de l'agent du transporteur émetteur Issuing Carrier's Agent Name and City

Renseignements comptables Accounting Information
SHPRS REF :WE576
JOB NUMBER:CDGAE94843B10

Code IATA de l'agent Agent's IATA Code
20-4 7248/9516

Numéro de compte Account Number

Aéroport de départ (Adresse du premier transporteur) et itinéraire demandé Airport of Departure (Address of First Carrier) and Requested Routing
PARIS/CHARLES DE ADD

N° de Référence Reference Number

Information Acheminement (Facultatif) Optional Shipping Information

à to	Par premier transport By First Carrier / Routage at Dest. Rout. and Dest.	à to	par by	à to	par by
ADD					

Monnaie Currency	Frais CHGS code	Poids/Val WT/VAL Payé PPD	Poids/Val WT/VAL Dû COLL	Autres Other Payé PPD	Autres Other Dû COLL	Valeur déclarée pour le transport Declared Value for Carriage	Valeur déclarée pour la douane Declared Value for Customs
EUR		P		P		NVD	NCV

Aéroport de destination Airport of Destination

Vol/Date Demandés Requested Flight/Date
ET 3717/23

Montant de l'assurance Amount of Insurance

ASSURANCE - Si le transporteur propose une assurance et que l'expéditeur en fait la demande conformément aux présentes conditions, indiquer le montant à assurer en chiffres dans la case "Montant de l'assurance".
INSURANCE - If Carrier offers insurance, and such insurance is requested in accordance with conditions on reverse hereof, indicate amount to be insured figures in box marked "Amount of Insurance".

Renseignements pour le traitement de l'expédition Handling Information
FRET NON SECURISE
DO NOT SPLIT THE PLTS *** HANDLE WITHA CARE
TRACHOMA DONATION ** ADDIS ABABA ** ETHIOPIA

SCI
X

Nombre de colis Number of Pieces RCP	Poids brut Gross Weight	kg lb	Classif. de tarif Rate class / N° d'article de la marchandise Commodity Item No	Poids de taxation Chargeable Weight	Tarif/Montant Rate/Charge	Total Total	Nature et quantité des marchandises (y compris dimensions ou volume) Nature and Quantity of Goods (Incl. Dimensions or Volume)
399	56891.0K	Q		72233.5	4.57	330107.10	PHARMACEUTICAL PRODUCTS
	SHPRS REF : WE576, 005353			386029,	DTA, 87963	10, W4C64,	SLAC: 16249
	005354, QF0000 919, QF000 2913, 87 53800, 303 9,						
	QF00002920, 88 21870, GEN						
399	56891.0					330107.10	VOL: 433.400 CBM.

Port payé Prepaid: 330107.10
Taxation au poids Weight Charge:
Port dû Collect:

Autres frais Other Charges
MYC 25600.95 CHC 16.30 AWA 12.85
XDC 8533.65 SSC 265.00

Taxation à la valeur Valuation Charge:
Taxe Tax:

Total des autres frais dus à l'agent Total Other Charges Due Agent: 12.85
Total des autres frais dus au transporteur Total Other Charges Due Carrier: 34415.90

L'expéditeur certifie que les indications portées sur le présent document sont exactes et que, dans la mesure où une partie quelconque de l'expédition contient des marchandises dangereuses, cette partie d'expédition est correctement dénommée et bien préparée pour le transport par air conformément à la réglementation applicable.
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.
071 FRANCE SARL

Signature de l'expéditeur ou de son agent Signature of Shipper or its Agent

Total port payé Total Prepaid: 364535.85
Total port dû Total Collect:

Taux conversion monnaie Currency Conversion Rates:
Port dû en monnaie du pays de destination Collect Charges in Destination Currency:

18/FEB/2010 (Date) ROISSY CDG, PARIS (Lieu) RMARAUJO
Fait le Executed on (Date) à at (Lieu) (Place)
Signature de transporteur émetteur ou de son agent Signature of Issuing Carrier or its Agent

Réservé au transporteur à destination For Carrier's Use only at Destination

Frais à l'arrivée Charges at Destination:
Total dû Total Collect. Charges:

MAWB 071 - 1529 3600

ORIGINAL 2 (POUR LE DESTINATAIRE) *ORIGINAL 2 (FOR CONSIGNEE)*

MOD. 5071 — Vente par correspondance : GMJ Phoenix, 106 avenue Georges Clemenceau - 94366 BRY-SUR-MARNE Cedex - ☎ 01 48 82 51 51 - Fax : 01 48 82 51 59 - Site internet : www.gmjphoenix.com

Zithromax® Receipt Confirmation Form

From: (the country receiving the shipment)

To: ITI

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

Product Description	Quantity received in good condition (in bottles)	Quantity damaged/Lost (in bottles)	Total quantity shipped (in bottles)	Current storage location
1. Tablets				
2. POS (with cups)				

Note on the damaged/lost products:

Prepared by:_____ **Approved by_____**

Zithromax® Allocation Schedule

Zone	District	Total Population a	Gross Required amount		Stock on hand		Shipment amount	
			Tablets (Bottles) $b = \frac{a \times 0.8 \times 3}{30^*}$	POS (Bottles) $c = \frac{a \times 0.18 \times 10}{30^*}$	Tablets (Bottles) d	POS (Bottles) e	Tablets (in cartons) $f = \frac{b - d}{48\ **}$	POS (in cartons) $g = \frac{c - e}{48\ **}$

*Note: Quantities are based on current bottle size.

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

Stock Card

STOCK CARD

Zithromax® Tablets ☐ **Zithromax® POS** ☐

Storage Location:	**Storage Unit:** Bottles

Date	Transfer form serial no.	Origin/ Destination	Quantity Received (Bottles)	Quantity Issued (Bottles)	Losses/ Adjustments (Bottles)	Quantity on hand (Bottles)	Signature of the store in-charge

Physical Inventory Form

Date: _____ **Location: _____**

Product: Zithromax® Tablets ☐ or Zithromax® POS ☐

Expiry date	Storage location	Condition* (Short dated, Good, Damaged or Expired)	Number of complete cartons a	Number of bottles in partial cartons b	Total number of bottles c = (a × 48) + b

Counted by:_____(Name) **Checked by:_____ (Name)**

***Note:**

Short dated: Drugs that have less than 13 months of shelf life and usable
Good: Drug still has more than 13 months of shelf life and usable
Damaged: Drugs that are opened (partially used) or damaged
Expired: Drug with passed expiry date

Zithromax® Inventory Status Report

Organization: _____Program area: _____ Campaign Period:_____

Name of the distribution team leader: _____ Zone:_____ District:_____

Product name	Beginning balance	Amount received	Amount distributed	Losses/ Adjustment	Ending balance	Ending balance status		
						Expiring within next 1 year	Expiring within 1-2 year	Expiring after 2 years
Zithromax® tablet (Bottles)								
Zithromax® POS (Bottles)								

Notes on Losses/Adjustment: _____

Status of the empty bottles:_____

Status of Expired/Damaged drugs (if any):_____

Prepared by_____ Certified by_____ Approved by:_____

(Name and Date) (Name and Date) (Name and Date)

Transfer Form

Transfer Form

Serial No. **Date: _____**

Origin:_____ **Destination:_____**

Name and address of the carrier/person responsible:

_____
_____

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

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

Issuer:_____ **Carrier :_____**

(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:_____ **Carrier:_____**

ITI Customs Clearance Tool

Country _____
Date_____
Auditor_____

List the key informants

Name	Title
Name	Title
Name	Title
Name	Title

Begin the customs clearance investigation by first obtaining general information about the process used for this country. The respondent can either provide a graphical depiction of the process or a list of the steps and associated times. It is important to obtain the time it takes for the step to be complete and any fees levied at each step, if any.

Please provide a schematic of your customs clearance process for Zithromax® with procedure points, estimated time required (in days) to complete the step, and any fees required to complete the step. Alternatively, can you provide a list of the steps involved in getting the product into the country including the steps leading to an "approval to ship" the consignment, through the customs clearance process and transfer to the warehouse.

Step	Time to complete (# of days)

Who is the consignee?_____
_____

Who receives the donation? _____

What is the freight arrangement (e.g., door to door, door to port)_____
_____

Documents

In this section of the customs clearance investigation, you will obtain information about the documents used in the process of clearing the product through customs. If there are other documents used that are not identified in the questions that follow, please obtain that information anyway and report at the end of this section.

Which documents are required to clear product through customs and who provides them?

Document name	**Who provides the document?**
___ tax exempt certificate	_____
___ certificate of donation	_____
___ letter of agreement	_____
___ Bill of Lading/Air Waybill	_____
___ proforma invoice	_____
___ quality assurance certification/certificate of analysis	_____
___ inspection report	_____
___ packing list	_____
___ packaging and markings certifications	_____
___ Program approval letter	_____
___ Commercial invoice	_____
___ Importation license	_____
___ other:_____	_____
___ other:_____	_____
___ other:_____	_____

Have you experienced any delays in obtaining the required documents? If so, what do you feel caused the delay?

Were documents received by the consignee in advance of arrival of product at port?

Was the letter of donation and proforma available in a timely manner?

Do any documents specify the roles and responsibilities in shipping and clearing the products? If so, name them.

Is a tax exempt certificate available?

Is a tax exempt certificate readily obtained?

Is informal notification of the shipping date provided to port clearance staff, warehouse staff and program managers? If not to all these parties, then to whom is this information provided?

Does the consignee receive notice that products have been shipped? What is that document called?

Once the product has been shipped, are all the necessary details from the Bill of Lading/Air Waybill provided to the recipient/consignee including:

___ shipping details
___ quality assurance documents and certifications
___ packing list and commercial invoice

Did the correct parties receive the Air Waybill and/or Bill of Lading? Who must receive these documents?

Were required copies distributed? To whom were copies provided?

Do all of the documents accompany the products? If not, what documents tend to be missing?

Product details and movement of the product

These questions will look at how the product moves through the customs clearance process as well as issues around its handling immediately after clearing customs. If the respondent can provide additional information than that which is sought through the questions, please note it as well.

How many days from arrival at port to receipt by consignee?

How many days from arrival at port to clearance of the goods?

Who clears the products?
___ broker/local transport agency
___ consignee
___ other

What was the size of the consignment for the last shipment?
(Date of last shipment_____)
_____ tablets
_____ POS
_____ cups

Was a pre-release inspection conducted? Who conducted it?

Was warehouse space for storage of product arranged in advance?

Was the warehouse informed of the arrival of the product when the estimated time of arrival (ETA) was determined?

Was the program office notified when the ETA was determined?

Was a distribution plan available at the time of arrival of product at port or during the clearance process?

At what point did the "owner" or consignee examine the shipment for quality (obvious physical damage, not chemical analysis) and quantity checks of the products? (i.e., verification of the product)

Who performed the quality and quantity checks?

How many days between clearance and movement of product to the warehouse?

Who arranges for:

- unloading of the shipment at the port of entry?
- clearance from the port and customs?

Is the product sufficiently protected while in transit from port to warehouse? (e.g., protected from inclement weather)

Does the warehouse staff inspect the goods for:

___ correct commodity
___ shipping damage
___ full quantities delivered and documented by lot number
___ packing slip present and correct

___ correct marking on packaging, including expiry dates
___ manufacturers certifications included with the shipment (or with the documents)

Does the warehouse staff immediately report any problems found during inspection?

To whom do they report?

Is there any additional information you can share regarding the handling of the products and their movement during the customs clearance process or its initial movement following clearance?

Fees

This section attempts to capture information about the fees involved in the customs clearance process and who is responsible for them.

Can you tell me what fees are involved in clearing the product through customs and who is responsible for those fees?

Fee	**Fee basis (e.g., % of value) Or whether the fee is waived for this product**	**Entity responsible for payment (e.g., consignee, shipper)**
Insurance		
Freight costs		
Taxes		
Duties		
Demurrage charges		

Additional notes

Zithromax® Supply Chain Audit
International Trachoma Initiative

Quantitative Tool
Interviewer's Guide

Facility Identification	Record the name of the facility and location. Using the codes provided for each question, place all other responses in the boxes on the right.
Information about Interview	Record the date the interview took place and list the names of the interviewers.
Introduction	Use the text here to guide your introduction of the survey to facility staff.
Questions 01 to 04	Receive permission to conduct the interview and record information regarding the interviewee.
Questions 101 to 112	Record responses by clearly circling either the number or letter that corresponds to the interviewee's response. Questions with letters may have multiple responses; questions with numbers have only a single response.
Table 1: Stock Status	To fill in the cells, follow the instructions above the table.
Table 2: Storage Conditions	Record observations on the main storage area (even if it is a cabinet) by responding to storage conditions 1 to 12 for every facility visited. For large storage areas that require stacking of multiple boxes, continue to complete storage conditions 13 to 17.
Table 3: Data Quality	Complete the table for all products.
Table 4: Quantity Ordered/Rec'd	Complete the table for all products.
End Interview	Ask the interviewee/s if they want to ask you any questions. Thank them for their time and cooperation.

Facility Services and Infrastructure

Facility Identification

Name of the facility _____

Facility location

City/town: _____

Region _____

District _____

Country

Facility Type: (1=Warehouse; 2= service delivery point (SDP)	Warehouse/SDP..... ☐
If service delivery point (SDP), mark type of facility: (1=District hospital; 2=Rural hospital; 3=Health center; 4=Dispensary; 7=Other _____)	SDP Facility Type..... ☐
If Warehouse: mark level: (1=Central; 2=Regional/provincial; 3=District	Warehouse Facility Type..... ☐
Facility characteristics: Tarmac to the facility? (0=no; 1=yes)	Tarmac ..... ☐
Operational electricity on day of visit? (0=no; 1=yes)	Electricity ..... ☐
Operational water in the building on the day of visit? (0=no; 1=yes)	Water..... ☐
Operational telephone or radio on day of visit? (0=no; 1=yes)	External Communication ..... ☐

Information about Interview

Date: _____

DAY/ MONTH/ YEAR

☐☐ ☐☐ ☐☐☐☐

Auditors: _____

_____

Introduction

Introduce all team members and ask facility representatives to introduce themselves.

Explain the objectives of this survey:

Good day. My name is _____. My colleagues and I are representing the International Trachoma Initiative in the US and here in (country). We are conducting a survey regarding the health commodity logistics system that manages the drug Zithromax®, which is used to treat trachoma. We are looking at the availability of Zithromax® and information about how you order and receive this product. We are visiting selected health facilities throughout the country where this campaign is taking place; this facility was selected to be in the survey. The objectives of the survey are to collect current information on logistics system performance and stock status of Zithromax®.

The results of this survey will provide information to make decisions and to promote improvements for future scale up of the program. This is a system assessment. We are not here to conduct a supervisory visit and we are not evaluating your personal performance on the job. Please feel free to speak frankly with us.

We would like to ask you a few questions about the Zithromax® managed at this facility. In addition, we would like to actually count the products you have in stock today and observe the general storage conditions. Do you have any questions?

No.	Question	Code Classification	Go To
01.	Can we continue?	Yes ..... No	 ➔STOP
02.	Name and title and of person interviewed for this section		
03.	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
04.	Who is the principal person responsible for managing medical supplies at this facility?	Nurse ..... Clinical Officer ..... Pharmacy Technician ..... Pharmacy Assistant ..... Pharmacist ..... Medical Assistant..... Other (Specify) _____	

First, ask the following questions from the designated storeroom or facility manager. After asking these questions, visit the warehouse, storeroom, or storage area where the health products are kept. If your informant was not present when you introduced the goals and objectives of the audit, explain them to this person. Inform the respondent that you are interested in the trachoma program products only.

No.	Questions		Go To/ Comments
101.	Do you use and fill out the following logistics forms to manage health products?		
	A. stock cards	Yes ..... No	
	B. daily register	Yes ..... No	
	C. other ……	Yes ..... No	
	D. other ……	Yes ..... No	
	E. other ……	Yes ..... No	
102.	Do Logistics Management Information System reports include the following?		
	A. stock on hand	Yes ..... No	
	B. quantities used (dispensed or issued)	Yes ..... No	
	C. losses and adjustments	Yes ..... No	
	D. quantities received	Yes ..... No	
103.	How often are these LMIS reports sent to the higher level? *(Circle all that apply.)*	Monthly ..... Quarterly ..... Semi-annually ..... Annually ..... Other _____	
104.	How many facilities are supposed to send LMIS reports to this facility?	_____	
105.	How many facilities submitted complete LMIS reports for the month of _____ (two months prior to survey month)?	_____ Ask to see reports and check here if verified. _____	

106.	Did you place an emergency order for Zithromax® during the last campaign? If so, how long did it take to receive the supply?	Yes ..... No ..... Number of days to receive.....	
107.	Who determines this facility's resupply quantities? *(Circle all that apply.)*	The facility itself ..... Higher-level facility ..... Other_____	
108.	How are the facility's resupply quantities determined?	Formula (specify) _____ Don't know ..... Other means.....	
109.	On average, approximately how long does it take between ordering and receiving products?	Less than 2 weeks..... 2 weeks to 1 month ..... Between 1 and 2 months ..... More than 2 months	

110. Does the program conduct physical inventories of Zithromax® at this storage facility? Yes _____
No _____

(If yes, d*escribe timing and frequency)*

111. Have you had any stockouts of Zithromax® tablets, pediatric oral suspension (POS), or cups during the current treatment campaign? *If yes, please note the duration of stockout on the line to the right.*	Tablets ❑ Yes ❑ No_____ POS ❑ Yes ❑ No_____ Cups ❑ Yes ❑ No_____
112. At the conclusion of the last treatment campaign, (e.g., last year), did you have a left-over Zithromax® tablets, POS, or cups? If yes, what did you do with the extra Zithromax®?	Tablets ❑ Yes ❑ No_____ POS ❑ Yes ❑ No_____ Cups ❑ Yes ❑ No_____

Thank you for your time and information. You have been very helpful. Our remaining questions will require looking at products in the storeroom.

TABLE 1: Stock Status (since the beginning of the current campaign and on the day of visit)

Note: Columns 1 and 2 should be filled out before questionnaires are printed for the survey.

Column:

3. Check if the stock card is available, answer Y for yes or N for no.
4. Check if the stock card had been updated within the last 30 days, including lot numbers on all stock cards. Answer Y for yes or N for no. Note: If the stock card was last updated with the balance of 0 and the facility has not received any resupply, consider the stock card up-to-date.
5. Record the balance on the stock card.
6. Record if the facility has had any stockout of the product since the start of the treatment campaign, up to the day of the survey. Answer Y for yes or N for no.
7. Record how many times the product stocked out during since the start of the treatment campaign according to stock cards, if available, or to a key informant if not. Note source information.
8. Record the total number of days the product was stocked out since the start of the treatment campaign.
9. Record the quantity of product dispensed to users or issued from the storeroom since the start of the treatment campaign. Note: If the answer to column 3 is N, record NA in this column.
10. Record the number of patients treated since the beginning of the current treatment campaign (may need to refer to patient register or other report since this information is not likely to be available in the storeroom).
11. Record the quantity of product in the storeroom. Estimate to ¼ of a bottle for open containers or tablets.
12. Record if the facility is experiencing a stockout of the product on the day of the visit, *according to the physical inventory*, answer Y for yes or N for no.
13. Record the quantity of damaged (i.e., usable) products. Count all damaged products on the day of the visit.
14. Record the quantity of expired products. Count all expired products on the day of the visit. If there are products that are near expiry (within one week), note in the comments section.

Product	Units of count	Stock card available? (Y/N)	Stock card updated including all lot #s? (Y/N)	Balance on stock card	Stockout since start of campaign (Y/N)	If yes, number of stockouts	Total number of days	Total issued or dispensed (since start of campaign)	No. of patients treated since start of campaign	Physical inventory—Store room	Stockout today? (Y/N)	Quantity of damaged products	Quantity of expired products
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Zithro. Tablets	Bottles												
Zithro. POS	Bottles												
Measure cups	Cups												

a. Verify (spot check) that lot numbers on bottles/boxes and stock cards match.

b. For any product that experienced a stockout since the start of the treatment campaign (including the day of the visit), please note reasons (by product):

TABLE 2: Storage Conditions

Items 1–12 should be assessed for all facilities for products that are ready to be issued or distributed to clients. Place a check mark in the appropriate column based on visual inspection of the storage facility; note any relevant observations in the comments column. ***To qualify as "yes," all products and cartons must meet the criteria for each item.***

No	Description	No	Yes	Comments
01.	Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible.			
02.	Products are stored and organized in a manner accessible for first-to-expire, first-out (FEFO) counting and general management.			
03.	Cartons and products are in good condition, not crushed due to mishandling. If cartons are open, determine if products are wet or cracked due to heat/radiation (e.g., fluorescent lights, cartons right-side up).			
04.	The facility makes it a practice to separate damaged and/or expired products from usable products and removes them from inventory.			
05.	Products are protected from direct sunlight at all times of the day and during all seasons.			
06.	Cartons and products are protected from water and humidity during all seasons.			
07.	Storage area is visually free from harmful insects and rodents. (Check the storage area for traces of rodents [droppings or insects].)			
08.	Storage area is secured with a lock and key, but is accessible during normal working hours; access is limited to authorized personnel.			
09.	Products are stored at the appropriate temperature during all seasons according to product temperature specifications (i.e., <30°C).			
10.	Roof is always maintained in good condition to avoid sunlight and water penetration.			
11.	Storeroom is maintained in good condition (clean, all trash removed, sturdy shelves, organized boxes).			
12.	The current space and organization is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for foreseeable future).			

The additional standards below can be applied to any facility large enough to require stacking of multiple cartons.

No.	Description	No	Yes	Comments
13.	Products are stacked at least 10 cm off the floor.			
14.	Products are stacked at least 30 cm away from the walls and other stacks.			
15.	Products are stacked no more than 2.5 meters high.			
16.	Fire safety equipment is available and accessible (any item identified as being used to promote fire safety should be considered).			
17.	Products are stored separately from insecticides and chemicals.			

Additional guidelines for specific questions:

Item 2: In noting proper product arrangement, consider the shelf life of the different products.

Item 3: Check cartons to determine if they are smashed due to mishandling. Also, examine the conditions of the products inside opened or damaged cartons to see if they are wet, cracked open due to heat/radiation, or crushed.

Item 4: Conduct the discarding of damaged or expired products according to the facility's procedures (this may differ from one facility to another). Specify if procedures exist and note what they are.

Item 7: It is important to check the storage area for traces of rodents (droppings) or insects harmful to the products.

Item 8: This refers to either a warehouse secured with a lock or to a cabinet in a clinic with a key.

Item 16: Fire safety equipment does not have to meet international standards. Consider any item identified as being used to promote fire safety (e.g., water bucket, sand). Do not consider empty and/or expired fire extinguishers as valid fire safety equipment.

TABLE 3: LMIS Data Quality: Usable Stock on Hand at Time of Most Recent LMIS Report

Column:

1. List the same products as in table 1. Include only those products that are managed by the facility.
2. Get the most recent LMIS report showing the selected products, and record the stock on hand from the LMIS report in column 2.
3. Write the quantity of usable stock on hand from the stock records from the time of the selected LMIS report.
4. Calculate the percentage of discrepancy by subtracting quantities of stock on hand from the LMIS report (column 2) from quantities of stock on hand from stock records (from time of LMIS report [column 3], divide this by quantities of stock on hand from stock record [column 3], and multiply by 100).
5. Note the reasons for any discrepancy.

Method/Brand/Product	Usable Stock on Hand (at time of most recent LMIS report)			
	Inventory according to most recent LMIS report (bottles)	Inventory from stock ledger or stock cards from time of LMIS report (bottles)	% Discrepancy (col.3–col.2/col.3) *100	Reasons for discrepancy
1	2	3	4	5
Zithromax® tablets				
Zithromax® POS				
Measuring cups				

TABLE 4. Percentage Difference between Quantity Issued and Quantity Received

Column:

1. List the same products as in table 1. For each product, extra rows are allotted so that multiple issue and receipt vouchers can be reviewed and recorded (a maximum of the most recent four vouchers).
2. Enter the quantity issued for the last order period for which products should have been received (i.e., don't include open orders whose expected receipt date has not arrived).
3. Enter the date the order was issued.
4. Enter the quantity received in the last order.
5. Enter the date the order was received.

Product	Quantity Issued for Last Order Period (bottles)	Date Order Issued	Quantity Received in Last Order (bottles)	Date Order Received
1	2	3	4	5
Zithromax® tablets				
Zithromax® POS				
Measuring cups				

Ask the person/people you interviewed if they want to ask you any questions.

Comments or general observations on products management:

Thank the person/people who talked with you. Reiterate how they have helped the program achieve its objectives, and assure them that the results will be used to develop improvements in logistics system performance.

Notes/Comments:

Notes

Notes

Notes

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