

## **Rapid Assessment of Zithromax Management for Trachoma Treatment in Ethiopia: Final Report, August 2013**

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This report is prepared under the terms of contract between the International Trachoma Initiative (ITI) and Management Sciences for Health (MSH) to conduct Zithromax management assessment in Ethiopia. The contents are the responsibility of the authors of the document and do not necessarily reflect the views of ITI or MSH.

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## **Recommended Citation**

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## CONTENTS

Acronyms and Abbreviations .....	iv
Executive Summary .....	v
Key Findings and Observations .....	v
Challenges in Zithromax Mass Drug Administration .....	viii
Opportunities for Success in the Anticipated Scale-up .....	ix
Key Recommendations for Scale-up .....	x
Introduction .....	1
Context .....	2
Objectives of the Assessment .....	5
Assessment Findings and Observations .....	6
Detailed Description of Current Zithromax Management .....	6
Inventory of Stock on Hand .....	20
Technical Resources Drawn upon by FMOH, PFSA, and RHBs for Supply Chain Management Training and Technical Assistance .....	23
Analysis of Current Buffer Stock Policy and Recommendation for Modifications .....	23
Progress Made in Relation to Recommendations Cited in 2009 Supply Chain Assessment Report for Ethiopia, Conducted by John Snow, Inc. ....	23
Recommendations for Addressing Supply Chain Management Weaknesses or Gaps .....	25
Plan of Action .....	25
Quality Assurance and Medicine Safety Monitoring (Pharmacovigilance) .....	25
Annex 1: Key Persons Met .....	27
Annex 2: District (Wereda) Checklist: Donated Zithromax Supply Chain/Logistics Management .....	28

## ACRONYMS AND ABBREVIATIONS

ADR	adverse drug reaction
AMR	antimicrobial resistance
FEFO	first-expiry, first-out
FHF	Fred Hollows Foundation
FMHACA	Food, Medicine and Health Administration and Control Agency
FMOH	Federal Ministry of Health
GTM	Grarbet Tehadiso Mahber
HC	health center
HEW	health extension worker
IPLS	Integrated Pharmaceutical Logistics System
ITI	International Trachoma Initiative
LFW	Light for the World
LMIS	logistics management information system
MDA	mass drug administration
MFM	Menschen für Menschen
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
NTD	Neglected Tropical Disease
PFSA	Pharmaceutical Fund and Supply Agency
POS	pediatric oral suspension (Zithromax)
RHB	Regional Health Bureau
SAFE	Surgery, Antibiotic, Face Washing, and Environmental Improvement (trachoma strategy)
SAE	serious adverse event
SOP	standard operating procedure
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SNNPR	Southern Nations, Nationalities and Peoples Region

## EXECUTIVE SUMMARY

This report presents the findings of the Zithromax® supply chain assessment together with recommendations. The objective of this assessment is to determine supply chain and logistics management capabilities and challenges of the Federal Ministry of Health (FMOH); the Pharmaceutical Funding and Supply Agency (PFSA); Regional Health Bureaus (RHBs); districts; and implementing partners of Amhara, Oromia, Tigray regions and the Southern Nations, Nationalities and Peoples Region (SNNPR) to effectively manage the projected scale-up of the Zithromax donation to Ethiopia over the coming years in support of eliminating blinding trachoma as a public health problem by 2020. The assessment covered areas related to customs clearance at ports-of-entry as well as in-country storage, transportation, inventory management and control, any diversion of donated Zithromax into to commercial sector, and reverse logistics practices at the central, regional, district, and community levels. These findings are based on the responses to questionnaires from four regions, 11 districts, nine *kebeles*, six partners, and PFSA.

Overall, the management of Zithromax has been found to be going well, probably because nearly the whole operation benefits from partner support and commitment. Weakness of regional, zonal, and district ownership of the process is apparent as well as weak coordination and collaboration between partners. PFSA plays a pivotal role in clearing and storing Zithromax. Although it has the capacity to do so, PFSA does not carry out the storage and distribution tasks at peripheral levels. The impending scale-up can be handled only if the challenges, best practices, and gaps existing at the current level of Zithromax management are better understood.

### Key Findings and Observations

- Eight partners (the Carter Center, Orbis, World Vision, Fred Hollows Foundation [FHF], Grarbet Tehadiso Mahber [GTM], AMREF, Light for the World [LFW], and Menschen für Menschen [MFM]) operate in different districts in targeted regions implementing the Surgery, Antibiotic, Face Washing, and Environmental Improvement (SAFE) strategy for the control of trachoma. Although all partners are involved in the antibiotic component of the strategy, not all are fully engaged in the other aspects. Sometimes they create informal partnerships with those with resources and expertise in the other components. The Carter Center manages more than 60 percent of the target districts, but its work is currently limited to the Amhara Region. Partners focus support on mass drug administration (MDA) campaign training, transport of Zithromax to campaign districts and sites, payment of allowances for personnel involved in the distribution exercise, data collection, and submission of reports.
- In a couple of instances, Zithromax distribution was discontinued after two or three rounds (at times without conducting impact assessments), mainly because of shortage of financial or other resources. Such discontinuations were not planned well ahead (which should have been based on an exit strategy, such as transfer of responsibility to another partner or systematic handing over to the region or district). This practice can have implications for community relations, confidence development, and treatment outcome.

- The International Trachoma Initiative (ITI) Ethiopia plays a critical role in forecasting quantities of Zithromax needed by communicating with partners; expedites all donation applications and shipping-related activities; assists partners on timely access of Zithromax from the FMOH/PFSA; and maintains current updates on stock status, uptake, and reporting to ITI/USA. Although no shortage of Zithromax was reported, forecasting—which is mainly based on population census and prevalence—did not include provisions for buffer stock, assumptions that affect order quantity, balance on hand, expiry potential, or lead time.
- PFSA is responsible for clearing all shipments received in country. Currently all shipments are air-freighted, making clearing and logistics of moving products easier. As long as the necessary documents are received, clearing is done expeditiously. Although sea shipment may be less costly, poor experiences in the past resulted in preference for using the air-freight option.
- PFSA is the national medical store responsible for clearance, warehousing, and distribution of Zithromax to approved partners. It has 17 modular warehouses and plans to build 8 more (bringing the total to 25 hubs) for geographic coverage and expedited direct delivery to all health centers (HCs) and hospitals nationwide.
- The Integrated Pharmaceutical Logistics System (IPLS) is a transaction mechanism in place that is used by all health facilities to base their supply request on consumption and inventory on hand.
- The distribution chain (logistics, paper trail, and collection of campaign reports and redistribution of unused Zithromax) from PFSA to the partners, from partners to districts, and from districts to communities for mass distribution is well organized and smooth. The only challenge reported in some areas is the delay in reports from communities after MDA campaigns and delays in return of unused Zithromax from communities.
- All Zithromax is stored at two of PFSA's three rented warehouses in Lebu community, in the outskirts of Addis Ababa. The warehouses also contain other program and FMOH supplies. Storage conditions are satisfactory and adequate. PFSA has its own modular warehouses at the center and in selected zones in the regions, including a store-in-a-box modular store being completed at the central site (with another larger one envisaged in the very near future).
- District storage (either at the district office or HC) is generally below the standard in terms of space, condition, and storage accessories such as shelves and pallets. Storage of Zithromax at the district level is limited to holding for few days before MDA. The only Zithromax stored for relatively longer period is returned stock. Pharmaceutical storage at most districts faces challenges such as lack of organization, inadequate space, cleanliness, and commingling with nonmedical commodities. These have the potential to affect quality of the products and make inventory control difficult. The following pictures below are typical of such observations.
- About half the visited districts showed a weak logistics management information system in practice. The use of bin cards or stock cards for recording transaction and document balances, expiry, and batch numbers is not widely applied or not updated regularly. Without such tools, it is impossible to know stock levels and make decisions for redistribution.



- Each of the partners has introduced household registers to be used during campaigns that can be used for several campaign rounds. The partners are key in collecting and aggregating such data and producing a report. In some places preprinted registers are used. The registers and other forms used for Zithromax distribution and reporting vary from partner to partner, which indicates absence of standardization or harmonization of tools and forms. Except with the partners, the Zithromax program’s manager guide is not available at the regional and district levels. There are no country-specific standard operating procedures (SOPs) for the management of Zithromax. The presence of such an SOP could create uniformity of procedures and processes.
- Ethiopia has developed a national pharmaceutical waste disposal guideline. Although large quantities of expired Zithromax do not exist, the assessment found quite an accumulation of empty Zithromax containers at district stores. The absence of a clear guideline on disposal or reuse of empty containers and their storage at district facilities was mentioned by several interviewed persons as a challenge.
- A national guideline governs pharmacovigilance, containment of antimicrobial resistance (AMR), adverse drug reaction (ADR) reporting, and disposal of expired and unusable pharmaceutical products. Although the assessment did not find serious adverse events (SAEs) reported as a problem, other ADRs are mentioned to be commonly encountered. At times because of weak public awareness and community education, instances of low coverage were reported. The ADRs experienced are not documented or reported on any of the available forms and hence do not receive attention and follow-up.
- Use of health extension workers (HEWs) as the lead in Zithromax distribution in collaboration with community Development Army members is an innovative community outreach initiative that can ensure higher coverage through mass campaigns or house-to-house contact. The presence of more than 38,000 HEWs with support of Health Development Army members in every community makes mass or house-to-house distribution dependable and sustainable, and their participation instills ownership in the program.

- The stringent regulation that limits sale of antibiotics to prescription only, coupled with partner monitoring of Zithromax stock management at community and district levels, seems to have prevented diversion of donated Zithromax to the private market.
- The FMOH has newly formed case teams, two of whose members have a bearing on Zithromax distribution. The logistics case team has a focal person for Zithromax who communicates directly with PFSA and partners and will have relevant stock status and related information in a more organized manner. The neglected tropical disease (NTD) case team is formed to focus on the different NTDs and has trachoma focal person, which is hoped to make communication and planning more efficient.
- As part of the integration strategy, the direction seems to be to use the existing health system for managing Zithromax at all levels. This includes using PFSA to deliver to districts or HCs (through its zonal hubs and fleet of vehicles), as is done with other program products and essential medicines, and relying on HEWs and members of the Health Development Army to conduct the mass campaign. This means partners will need to provide resources, support, and technical assistance to these structures to implement the program.
- The Food, Medicine and Health Administration and Control Agency (FMHACA) is the regulatory arm of the government that can effectively be used in providing guidance and support in the areas of disposal of expired and unusable products, pharmacovigilance/ADR reporting, and regular inspections of private outlets for evidence of diversion of donated products.

### **Challenges in Zithromax Mass Drug Administration**

- Despite the willingness and readiness of partners to get involved, they need to mobilize additional resources so they can provide required technical support for mass campaigns and implementation of the complete SAFE strategy as a long-term commitment.
- Although PFSA has the capacity, experience, and willingness to get fully involved beyond clearance, central storage, and supply of Zithromax to partners from its central warehouses, it will be desirable and important for PFSA to use its peripheral hubs to store and deliver Zithromax to the districts or other appropriate mechanisms of the campaign. For this to happen, PFSA needs additional resources that could be facilitated by the FMOH or other donors.
- A few communities were found to have conducted more than seven campaigns. In principle, a high-prevalence area can be effectively managed with four rounds of Zithromax treatment. One of the reasons for the additional rounds mentioned by interviewed persons is that the Zithromax treatment is not always supported by the full set of three components of the SAFE strategy. Although most of the partners are effective in the surgery and antibiotic components, the environmental hygiene, sanitation, latrines, wells, and face washing are lagging behind. Although this is one of the preconditions of the Memorandum of Understanding (MOU) between ITI and the FMOH, close follow-up and consultation will be essential.

- It has been reported from isolated quarters that initial ADR experiences had slowed uptake in subsequent campaigns. However, this has been corrected with heightened public education. Although SAEs have not been reported, preparedness in following up with reported or observed ADRs seems to be weak. The national government agency for regulatory affairs, FMHACA, has a system for reporting ADRs as part of its pharmacovigilance activities. Unfortunately, ADRs from Zithromax treatment are not reported through this channel. It will contribute to the safety profile of the campaign if the national guidelines are followed.
- The assessment team has learned that a partner discontinued its Zithromax mass drug administration (MDA) support to a district because of resource constraints. There was no evidence of organizing a smooth pull-out and exit strategy. At the time of the assessment there was no replacement partner to carry subsequent MDAs for two years. Such an abrupt and unplanned exit has resulted in a discontinuation of the previously started treatment and could have implications in future treatments as well as result in loss of trust for partners. The presence of an MOU that defines modalities of discontinuation could have saved the situation.
- Zithromax MDAs were disrupted in two districts in Tigray where the MDA was conducted as an RHB activity without the support of a partner. Resource constraints led the region to discontinue the MDA for the last three years. Such unplanned start-up and disruption has implications in treatment outcome. Any entity starting an MDA is strongly advised to make sure the right resources and multiyear commitments are in place at the outset.

### **Opportunities for Success in the Anticipated Scale-up**

- The heightened commitment of the FMOH is demonstrated by the creation of the NTD and trachoma focal teams dedicated to the coordination, reporting, and collaboration with stakeholders and partners.
- In addition to the existing central and branch warehouses and systems, PFSA is building more modern central and peripheral branches (hubs) supported by robust inventory and information management systems.
- PFSA has fleet of trucks for direct delivery of products to health facilities in addition to its capacity to use dependable third-party private transport outfits.
- The FMOH is strongly behind its proven strategy of using HEWs and Development Army to reach every household in all the country's communities. With more than 38,000 HEWs and hundreds of thousands of community Development Army members, this structure makes implementation of the scaled-up Zithromax distribution feasible and effective. The HEWs have already demonstrated their ability to shoulder similar responsibilities, and this program will not interfere with their other activities because the Zithromax distribution is of limited duration during the year.
- The existing partners, such as the Carter Center, Orbis, World Vision, GTM, and MFM, have many years of experience in trachoma control and Zithromax distribution in MDAs. Each

partner has used different approaches in supporting MDAs, providing valuable lessons that can contribute to the scale-up and continuity of the program.

- The Carter Center is implementing an impressive regionwide Zithromax distribution in Amhara and has been mobilizing mass administration of Zithromax for more than 9 million persons in only a week. Such operations can be a best practice for other partners and regions to learn from for large-scale MDA in a short period of time.
- The Carter Center has combined malaria testing, treatment, and mosquito net distribution with Zithromax mass administration under the operational nomenclature of MalTra. Such best practices can be a model to look at for integrated disease management that can be used by other partners to go to scale with their existing operations.
- The addition of the FHF, supported by the UK Department for International Development and LFW, and the return of AMREF after two years of absence are a welcome addition to the partner map.
- The participation of partners such as World Vision and MFM brings best practices of implementing the comprehensive SAFE strategy, because their mission includes community development activities such as water and sanitation as well as community economic and social development initiatives.
- ITI/Ethiopia has played a pivotal role in multiple activities that ensure coordination in Zithromax shipping, storage, distribution, reporting, training, supervision, and reporting. Despite limited staff and operational field challenges, it has succeeded in playing the liaison role in all programmatic aspects. This experience can contribute in furthering the scale-up process with additional resources.

### **Key Recommendations for Scale-up**

- Build on PFSA's experience of Zithromax logistics management for better efficiency and integration—
  - PFSA should expand its Zithromax logistics services (storage, distribution, and inventory control) by working directly with the target districts, using its hubs in the different regions and zones. Because this service does not recur throughout the year, presumably it will not be a burden to PFSA.
  - PFSA should consolidate the current storage of Zithromax at two stores at Lebu to one at the central Addis Ababa warehouse.
  - PFSA should ensure monthly or quarterly reporting to ITI/Ethiopia through the FMOH, including stock on hand and at the different storage locations, quantities distributed, and to whom and when, including expiry dates and batch numbers.
- The FMOH, PFSA, and partners should work closely with target districts to thoroughly and systematically quantify and forecast annually, including buffer and safety stock

considerations. This will contribute to avoiding stock-outs, emergency orders, and overstocks.

- The FMOH and partners should find the required support and resources to address the chronic storage inadequacies for handling of Zithromax and related products at district, HC, and health post levels.
- The FMOH in collaboration with partners should harmonize and standardize community registers, inventory control tools, and training materials. Partners, in collaboration with the FMOH, need to print adequate registers and appropriate tools and distribute these to districts for onward distribution to communities and HEWs.
- The FMOH should maintain a central data hub where all Zithromax-related information, such as uptake, stock status, pipeline information, and treatment rounds, is actively maintained and accessible to ITI and other key players.
- HEWs should keep the community register at their premises so these registers are used in subsequent MDAs.
- The FMOH in collaboration with PFSA, partners, ITI/Ethiopia, and other relevant bodies should develop practical and clear SOPs or guidelines for PFSA, regions, zones, districts, and communities regarding Zithromax ordering, issuing, storage, distribution, MDAs, reverse distribution, proper inventory control and record keeping, reporting, segregation and documentation for disposal of expired or obsolete products, and management of empty containers.
- The FMOH in collaboration with ITI should provide guidance for the immediate disposal of all expired and unusable Zithromax that is currently held at all locations.
- The FMOH in collaboration with ITI should provide guidance for the immediate disposal or recycling and reuse of empty containers currently held at all locations.
- The FMOH should engage agencies such as the FMHACA and other relevant international and local bodies in training and reporting on ADRs and SAEs following Zithromax MDAs, in accordance with the national ADR/pharmacovigilance guideline.
- Partners and donors should encourage and support the FMOH in the identification and conduct of operations research that will contribute to the improvement, cost-effectiveness, efficiency, and safety of Zithromax management, MDAs, and the SAFE strategy.
- The FMOH should promote local ownership (regional, district, community) of Zithromax management and related activities for sustainability and accountability by involving relevant FMOH agencies, regions, zones and districts, and pharmacy units of these structures at every step of the planning, forecasting, training, inventory management, and reporting processes.
- Pfizer should ensure delivery of complete documents on time to PFSA for clearing shipment with copies to ITI/Ethiopia and the NTD case team to expedite smooth and timely clearing of the shipment and avoid keeping Zithromax on the tarmac at the airport before it is transported to the PFSA warehouse.

- Although the change of packaging from 30-tablet bottles to 500 bulk tablet bottles is reported to have logistics or cost advantages, the assessment team believes that inventory control, safety, and stability values could be brought about if such bulk presentation is done in strip packaging.
- MSH in collaboration with ITI and the FMOH should conduct a postassessment report dissemination and Zithromax management scale-up action plan development workshop for key stakeholders, partners, and other relevant bodies. This can also be a platform for bringing partners and stakeholders together to share their best practices and challenges as a forerunner to the recommended capacity-building workshop below.
- ITI in collaboration with the FMOH should hold an all partner and stakeholder supply chain skills-building workshop before the projected scale-up plans. This can be done region by region and should include pharmacy and PFSA personnel who will play key roles in pharmaceutical management. This platform will also enable new partners to learn from experienced implementing partners such as the Carter Center. This exercise will also help in the standardization of Zithromax supply chain management in Ethiopia (forecasting, distribution strategies, inventory counting and reporting, reverse logistics, and product use among partners with solutions specific to the conditions on the ground).
- The FMOH as the owner of the program should establish a coordinating mechanism that has all the active partners; regional, zonal and district representatives; donors; and other relevant bodies as members for promoting collaboration, mobilizing resources, sharing experiences, and building consensus for better outcomes.

## INTRODUCTION

ITI/USA engaged the services of Management Sciences for Health (MSH) to conduct a rapid assessment of Zithromax logistics management, including capacity, and a readiness assessment for the anticipated large scale-up of Zithromax treatment from the current 15 million treatments to about 45 million in 2014, a threefold increase in Ethiopia. ITI/USA has signed an MOU with the Ethiopian FMOH to manage Pfizer-donated Zithromax in the treatment of trachoma.

The Zithromax assessment was conducted August 5–15, 2013. Gabriel Daniel of MSH and Noah Kafumbe of ITI/USA were joined by four MSH/Ethiopia region-based senior technical advisers to conduct the assessment in four regions (Amhara, Oromia, SNNPR, and Tigray). Central-level interviews were conducted by Daniel and Kafumbe, focusing on the FMOH, PFSA, FMHACA, and several partners (the Carter Center, World Vision, Orbis, FHF, and GTM). MSH prepared five different checklists for collecting information on Zithromax from partners, regions, districts (*weredas*), *kebeles* (communities), and PFSA. The field assessment team had a preassessment briefing and orientation, and a postassessment review meeting with Daniel and Kafumbe to discuss the findings and observations and obtain clarification on the completed checklists. Daniel, Kafumbe, and the ITI/Ethiopia team met with Dr. Kebede Worku, the State Minister of Health for the FMOH, and Mr. Oumer Shafi, the newly appointed FMOH NTD team leader, to brief and debrief them on the assessment. Both regarded the assessment as an important step in the scale-up planning. Daniel and Kafumbe also visited Butajira and Mojo districts to get a better understanding of Zithromax logistics management. While the four teams were conducting the regional assessments, Daniel and Kafumbe visited PFSA and its warehouses, visited the FMHACA, and met with the majority of partners to learn about the roles they play in trachoma MDAs and Zithromax management. This report is based on responses to questionnaires administered to PFSA, partners, regions, districts, and *kebeles*. The analysis focuses on district information gathered because the district was found to be the key link in the Zithromax distribution.

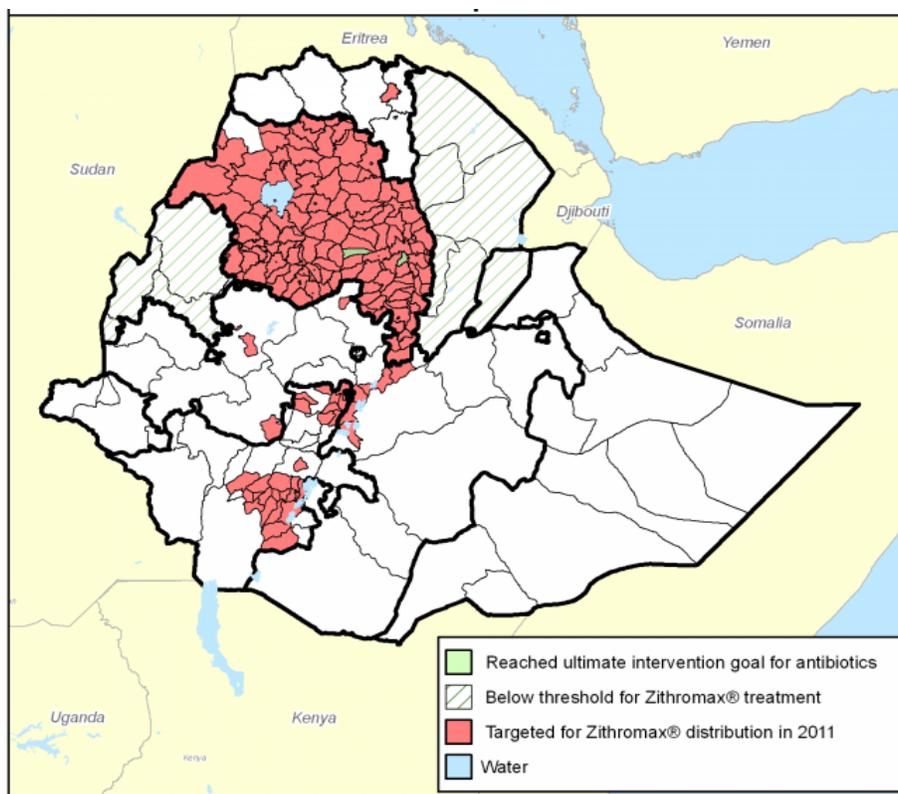


At left, the core assessment team (from left: Gabriel, Noah, Mlugetta, Getahun, Meressa, and Fikadu); at right, Noah checking Zithromax cartons at PFSA warehouse

## Context

The population of Ethiopia is estimated to be about 85 million. The country is divided into nine regions and two city administrations. The regions are divided into districts (called *weredas*). Each *wereda* is subdivided into *kebeles*, which are the lowest administrative units at the community level. Each *kebele* has a population of 5,000 and is served by a health post that is staffed by two female health workers called HEWs. There are about 38,000 HEWs nationwide. Of late, communities are organized into a Development Army that comprises five members to a cell. These final-miles human resource structures create the opportunity to reach each household to promote good health and community development.

Of Ethiopia's 85 million population, about 25.5 million are known to be at risk of trachoma. There are 209 confirmed endemic districts and 434 additional districts suspected to be endemic. ITI is supporting Ethiopia in its efforts to achieve the elimination of blinding trachoma by the year 2020. The Ethiopia national program has received more than 90 million Zithromax treatments since it began working with ITI in 2003. In 2011, ITI and the Ethiopia national program targeted about 22 million people for treatment. In Ethiopia, Amhara Region has the highest rate of active trachoma in children one to nine years of age (62 percent) and the highest rate of adults who have reached the final, blinding stage of trachoma (5.2 percent). Thanks to the Global Trachoma Mapping Consortium, health officials in the Oromia and Tigray Regions now know exactly where to plan trachoma elimination programs for more than 30 million people at risk, which covers 53 *weredas* in Oromia and 11 in Tigray. ITI in 2012 agreed to provide 15,310,331 treatments of Zithromax donated by Pfizer.



**Figure 1. 2011 Targeted Zithromax distribution in Ethiopia**

The FMOH is the national owner of the Zithromax program. The FMOH has signed an MOU every year to define the modalities of operation. The 2013 MOU between ITI and the FMOH in support of the elimination of blinding trachoma exclusively supports the distribution of Zithromax for trachoma control during the 2013 calendar year.

According to the MOU, the FMOH agrees to—

- Ensure free entry of Zithromax into the country and approved districts without imposing customs duty or tax or other costs, associated fees including clearing agent fees, taxes, documentation fees, demurrage fees
- Ensure Zithromax is distributed only in the districts where donation is expressly approved
- Obtain the necessary financial and human resources to support the distribution of the donated Zithromax
- Implement the full SAFE strategy in the districts in which Zithromax distributions occur
- Exclude children under six months of age from receiving Zithromax during distribution campaigns
- Ensure that product safety and quality monitoring and reporting processes are in place and reports are made to Pfizer through designated regional offices
- Ensure that donated Zithromax is used only for the control of trachoma and is not transferred or sold in exchange for money and distributed in a noncommercial fashion
- Cooperate with ITI, Pfizer, the Trachoma Expert Committee, and the respective affiliated entities and representatives to accomplish the objectives of the MOU
- Work with ITI to develop forecasts that will guide the manufacture, shipment, and distribution of Zithromax
- Cooperate with third-party consultants as identified by ITI to audit, assess, and improve the supply chain for shipment and distribution of Zithromax
- Submit bi-annual reports to ITI in the ITI report format (number of persons treated, results of prevalence surveys, stock on hand, quantities, expiry date, and precise location of the stock)

It will be essential to review adherence to the MOU at least bi-annually to ensure agreed upon norms are on track.

Table 1 shows indicative numbers of the projected scale-up of Zithromax donation needs in Ethiopia for the period 2014 through 2017,<sup>1</sup> compared with Zithromax donation distribution for the period 2009 through 2011. As can be seen, the Zithromax donation program in Ethiopia is

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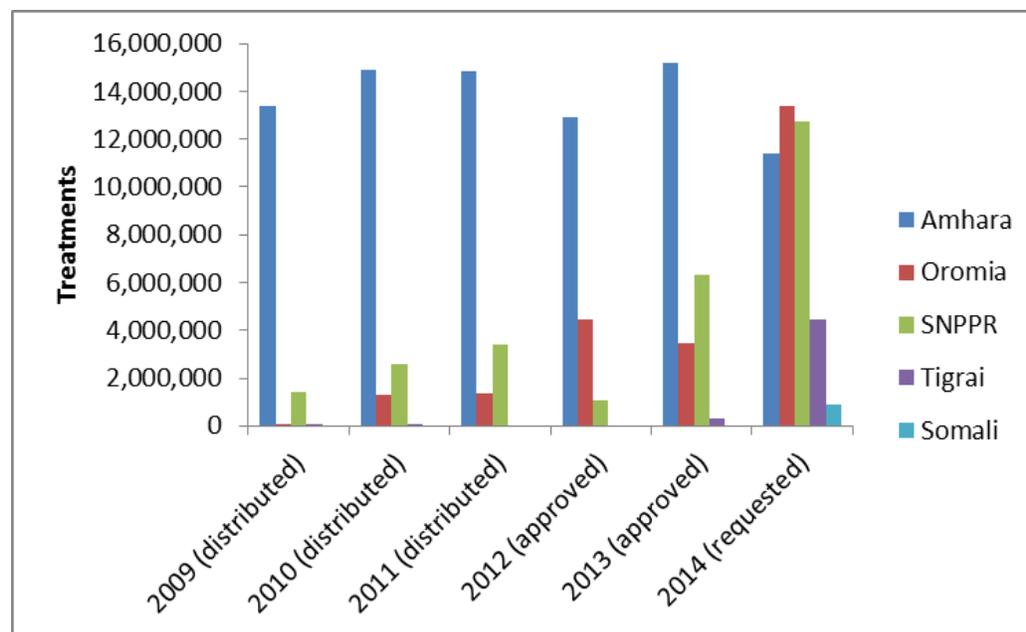
<sup>1</sup> Data for 2012 and 2013 distribution are presented at approved treatment levels.

scheduled to nearly triple by 2014 and to reach a sustained level of roughly 35 million to 36 million people treated over the three-year period 2015 to 2017. Ahmara Region is projected to begin scaling down as of 2015. Somali Region is projected to hold steady at roughly 900,000 treatments through 2017. Oromia Region and SNNPR are projected to have a more than fourfold increases while Tigray Region is projected for as much as an eightfold increase from 2013 to 2014.

**Table 1. Overview of Zithromax Donation in Ethiopia, 2009–2017**

Region	2009 Distributed	2010 Distributed	2011 Distributed	2012 Approved	2013 Approved	2014 Requested	2015 Forecast	2016 Forecast	2017 Forecast
Amhara	13,396,662	14,911,772	14,833,542	16,968,184	9,231,935	13,704,602	6,523,616	4,868,544	4,965,915
Oromia	794,809	1,279,595	1,352,449	3,012,166	2,377,788	<b>11,111,589</b>	9,662,471	9,628,003	9,391,951
SNNPR	1,415,793	2,606,205	3,418,115	5,165,470	4,020,141	<b>16,619,582</b>	17,051,691	17,137,090	17,325,838
Somali	0	0	0	0	0	<b>871,923</b>	871,923	889,361	907,149
Tigray	88,960	77,657	0	294,980	305,007	<b>2,415,812</b>	2,256,831	2,301,967	2,202,205
<b>Totals</b>	<b>15,696,224</b>	<b>18,875,229</b>	<b>19,604,106</b>	<b>25,440,800</b>	<b>15,934,871</b>	<b>44,723,508</b>	<b>36,366,532</b>	<b>34,824,965</b>	<b>34,793,058</b>

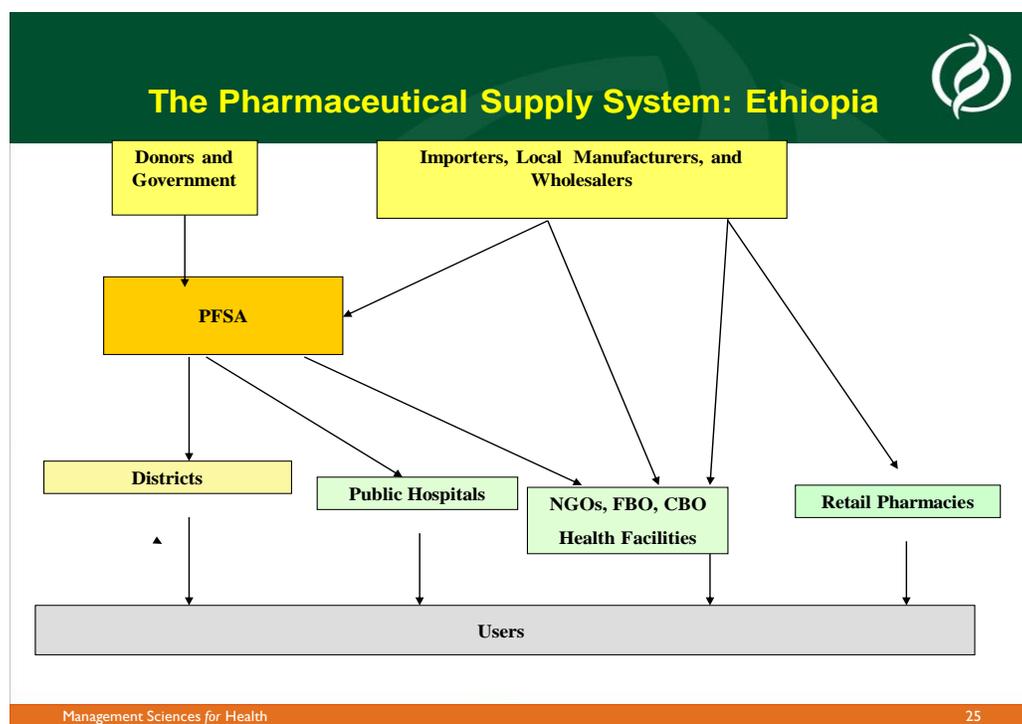
This unprecedented scale-up of the Zithromax donation makes it paramount that ITI conduct a supply chain and logistics field assessment in Ethiopia to ensure that the FMOH and its partners are ready for the scale-up.



Source: ITI, from table 1.

**Figure 2. Zithromax treatments, by region**

PFSA is an autonomous government agency responsible for the procurement, warehousing, and distribution of all pharmaceuticals and relevant health products to the public and not-for-profit organizations (see figure 3). With over 50 years of experience, the central medical store system has presence in all the regions of the country. It has modular warehouses and an optimal level of modern transport fleet fitted with cold-chain structures. PFSA has the requisite systems and capacity in place to effectively assume its responsibility as steward of donated Zithromax for eliminating blinding trachoma in Ethiopia.



Note: NGO = nongovernmental organization; FBO = faith-based organization; CBO = community-based organization.

**Figure 3. Ethiopian pharmaceutical supply system**

## Objectives of the Assessment

The objective of this assessment is to determine supply chain and logistics management capabilities of the FMOH, PFSA, RHBs, districts, and implementing partners of Amhara, Oromia, SNNPR, and Tigray regions to effectively manage the projected scale-up of the Zithromax donation to Ethiopia over the coming years in support of eliminating blinding trachoma as a public health problem by 2020. The assessment covers capacity areas related to customs clearance at port-of-entry as well as in-country storage, transportation, inventory management and control, and reverse logistics practices at the central, regional, district, and community levels. This assessment also investigates any diversion of donated Zithromax into the commercial sector. The final report includes deductions from the spot-checks for any diverted product, recommendations, and a plan of action for addressing these to strengthen in-country supply chain management capabilities in light of projected scale-up of the Zithromax donation in Ethiopia over the coming years.

## ASSESSMENT FINDINGS AND OBSERVATIONS

This section focuses on the key findings and observations from the assessment and is organized to address the terms of reference stipulated in the contract.

### Detailed Description of Current Zithromax Management

#### *Donation Structures, Systems, Processes, and Practices*

Eight partners (the Carter Center, Orbis, World Vision, FHF, GTM, AMREF, LFW, and MFM) operate in targeted regions and districts, implementing the SAFE strategy for the control of trachoma. Although all partners are involved in the strategy's antibiotic component, not all of them are fully engaged in other aspects. Sometimes they create informal partnerships with those with resources and expertise in the other components. The Carter Center manages more than 60 percent of the target districts, but its work is currently limited to the Amhara Region. Partners focus their support on MDA campaign training, transporting Zithromax to campaign districts/sites, paying allowances for personnel involved in the distribution exercise, collecting data, and submitting reports.

**Table 2. Partner Mapping in Trachoma in Ethiopia, 2013**

Partner	Target region	Number of districts	Population treated (approximate for 2012)	Remarks
Carter Center	Amhara	167 (76%)	10,505,795	Implemented as MalTra (integrated with malaria testing, long-lasting insecticide-impregnated net distribution, and artemisinin-based combination therapy)
Orbis	SNNPR	36 (16%)	4,264,930	Specialized eye care organization
GTM	Oromia SNNPR	9 (4%)	1,232,391	Indigenous nongovernmental organization with eye care and other medical services
World Vision	Oromia SNNPR	6 (3%)	892,492	Part of its integrated ADP project
MFM	Amhara	2 (1%)	137,376	Part of its integrated community development project
AMREF		NA	NA	Discontinued
Tigray RHB	Tigray	NA	NA	Discontinued after three rounds in two districts
FHF	Oromia	NA	NA	New, mapping and with high potential
LFW	Somalia Tigray	NA	NA	Mapping completed

*Note:* ITI/Ethiopia, Lions Clubs of Ethiopia, and the World Health Organization are also major contributors in the local campaign in Ethiopia. NA = not applicable.

As seen in table 2, in a couple of instances, Zithromax distribution was discontinued after two or three rounds (at times without conducting impact assessments), mainly because of shortage of financial or other resources. Such discontinuations were not planned well ahead (which should have been based on an exit strategy, transferring responsibility to another partner or systematically handing over to the region or district). This practice can have implications for community relations, confidence development, and on treatment outcome.

Findings from district informants indicate that partners conduct and provide almost all key support for Zithromax management. If Tigray Region is excluded, which in the past had managed all aspects of Zithromax management without assistance, partner involvement is 100 percent.

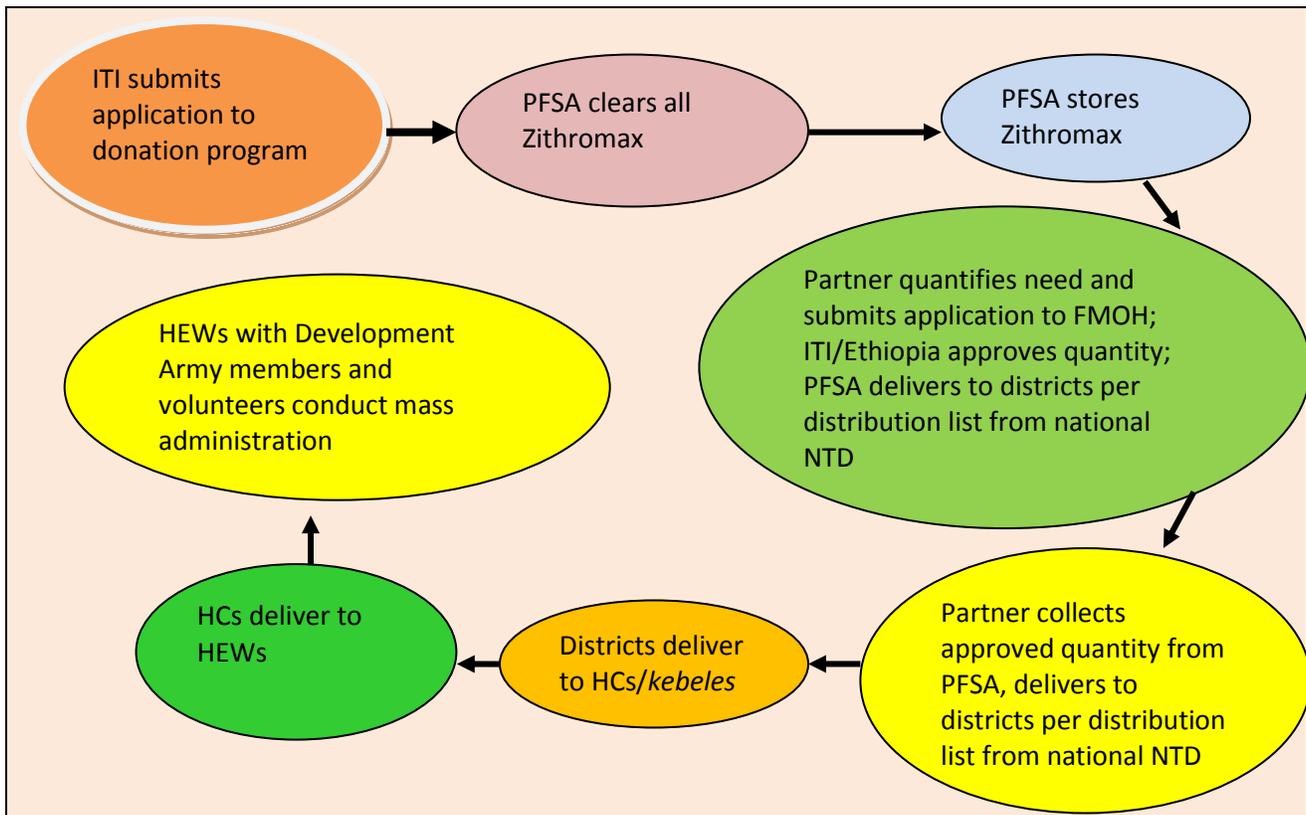
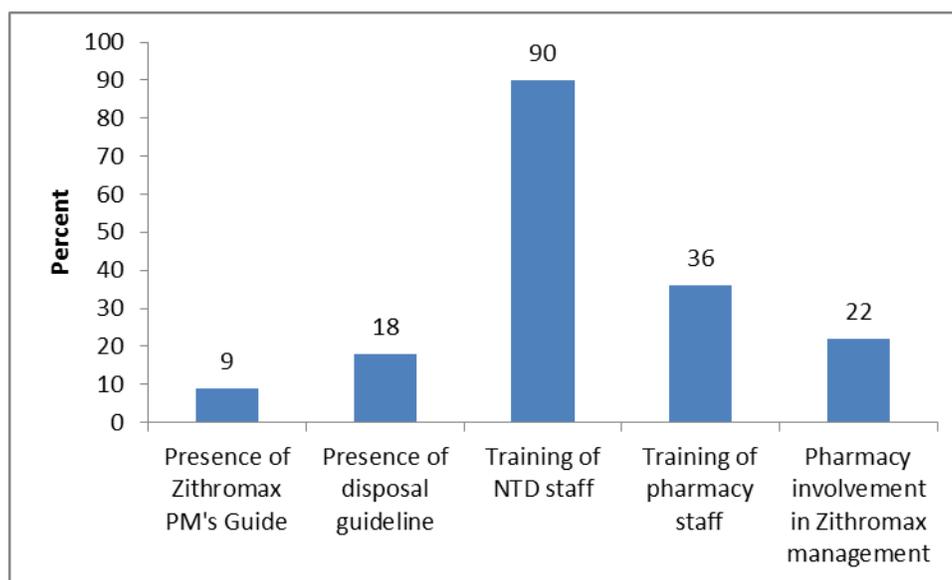


Figure 4. Zithromax management flow chart

As seen in figure 4, ITI/Ethiopia plays a critical role in forecasting by communicating with partners; expedites all procurement and shipping-related activities; assists partners on timely access of Zithromax from the FMOH/PFSA; and maintains current updates on stock status, uptake, and reporting to ITI/USA. Although no shortage of Zithromax was reported, forecasting is usually coordinated by the ITI country office and is based on census population and prevalence. The forecasting does not include consideration buffer stock needs, assumptions that affect order quantity, balance on hand, expiry potential, lead time, and so on.

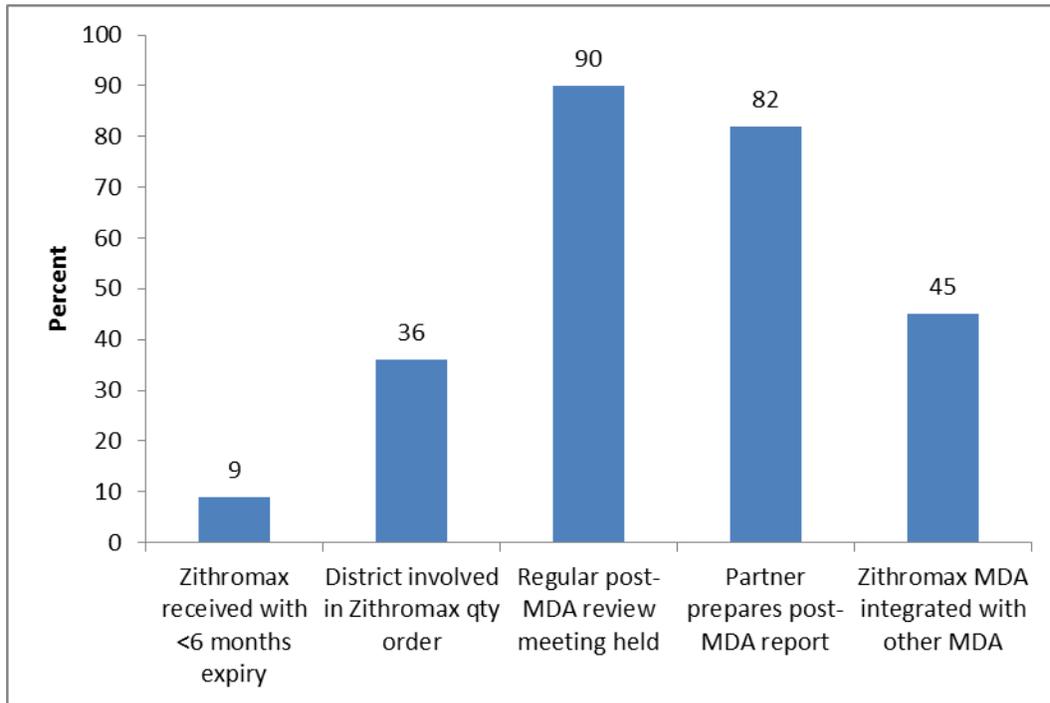
Thus the role of districts is minimal and not active, which has a bearing in sustainability and program ownership. The assessment looked at capacity building and availability of guidelines related to Zithromax management.

Figure 5 shows that only 9 percent of the districts assessed had the Zithromax program manager's guide. The guide needs to be produced and made widely available. Despite the presence of a national disposal guideline, only 18 percent of the assessed districts had the guideline. Because of the lack of the disposal information, unusable Zithromax has been kept in stores. Training in Zithromax is limited to campaign processes and not comprehensive; it does not cover logistics management, proper storage, and record keeping. Of district personnel, 90 percent are trained in Zithromax distribution, but only 36 percent of those trained are pharmacy personnel who usually are well placed to manage the products. The pharmacy units at all levels are minimally involved (only 22 percent) in the ordering, storage, distribution, and management of Zithromax. This is a missed opportunity because the pharmacy structure will be the eventual custodian of Zithromax at all levels.



**Figure 5. Availability of guidelines and district capacity relating to Zithromax management**

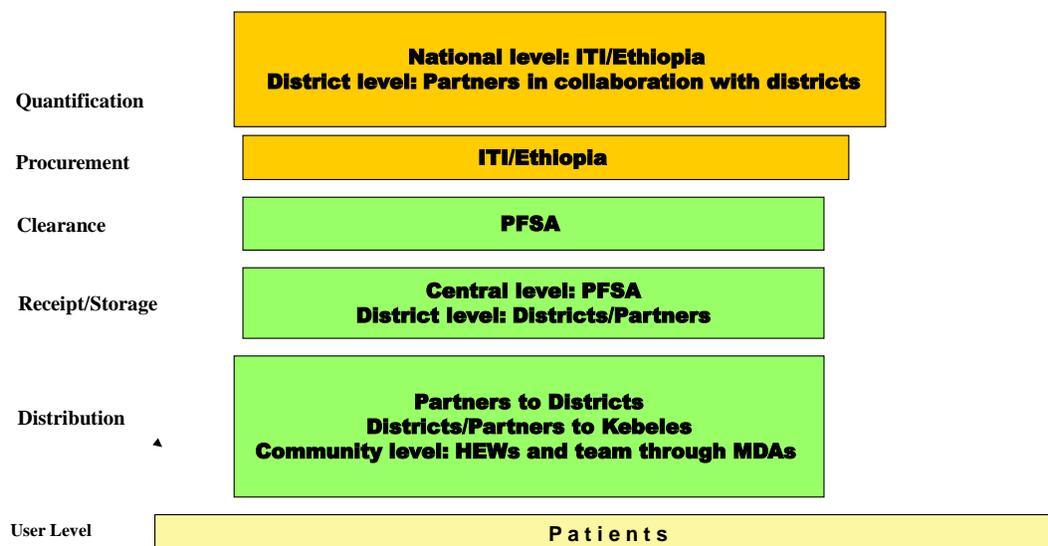
Figure 6 shows the status of district involvement in Zithromax management.



**Figure 6. District role in Zithromax management**

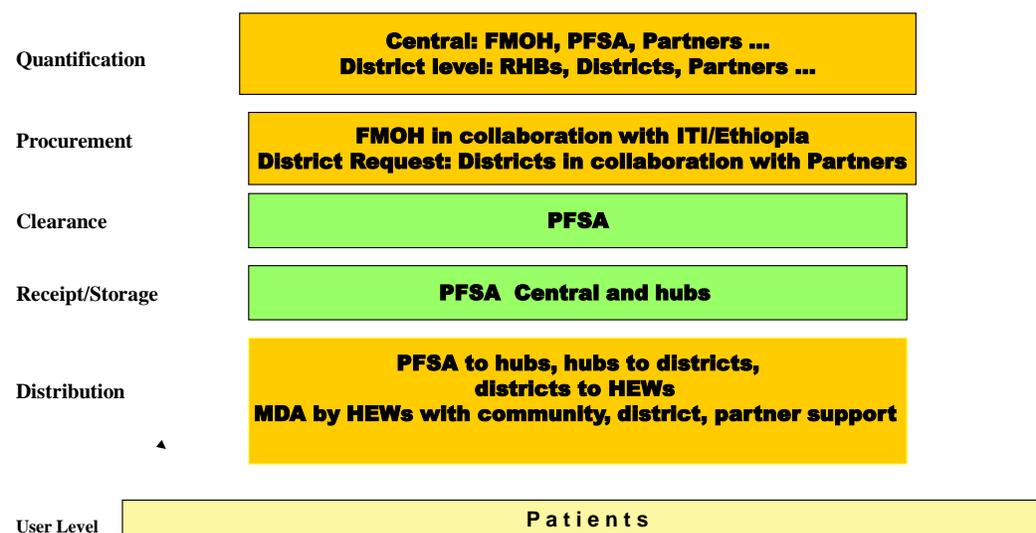
Over 90 percent of districts reported having received Zithromax with a remaining shelf life of more than six months, considered a best practice in distribution. Only 36 percent of districts said they are involved in actual quantification and forecasting, thus making their role passive recipients and not actively involved in the whole process from forecasting to distribution and reporting. Ninety percent of districts reported having conducted post-MDA campaign review meetings, which is a good practice to identify challenges and appreciate best practices to help in future campaigns. Partners (82 percent) rather than districts prepare and submit post-MDA reports. Such a practice does not give responsibility to the district, which is supposed to be the program owner.

### Current Zithromax Procurement and Distribution in Ethiopia



MSH MANAGEMENT SCIENCES for HEALTH  
RPM Plus | Rational Pharmaceutical Management Plus

### Recommended Zithromax Procurement and Distribution in Ethiopia



MSH MANAGEMENT SCIENCES for HEALTH  
RPM Plus | Rational Pharmaceutical Management Plus

Figure 7. Current and recommended Zithromax acquisition and distribution responsibilities

As seen in figure 7, the current practice of distribution uses PFSA for central storage; partners collect Zithromax on behalf of districts and transport it to districts. Although this system is logistically expeditious, it relies on the resources of partners and does not build sustainability and ownership by districts. The recommended practice involves using PFSA hubs to store and distribute to districts. The partners can focus more on assisting in the downstream distribution to the communities and on reporting from communities to districts. The FMOH has newly formed case teams, two of which have a bearing in Zithromax distribution. The logistics case team has a focal person for Zithromax who will communicate directly with PFSA and partners and have relevant stock status and related information in a more organized manner. The NTD case team is formed to focus on the different NTDs; it has a trachoma focal person, which is hoped to make communication and planning more efficient. As part of the integration strategy, the direction seems to be to use the existing health system for managing Zithromax at all levels. This includes using PFSA to deliver to districts or HCs, as is done with other products, and using HEWs and members of the Health Development Army to conduct the mass campaign. This means partners will need to provide resources, support, and technical assistance to these structures to implement the program.

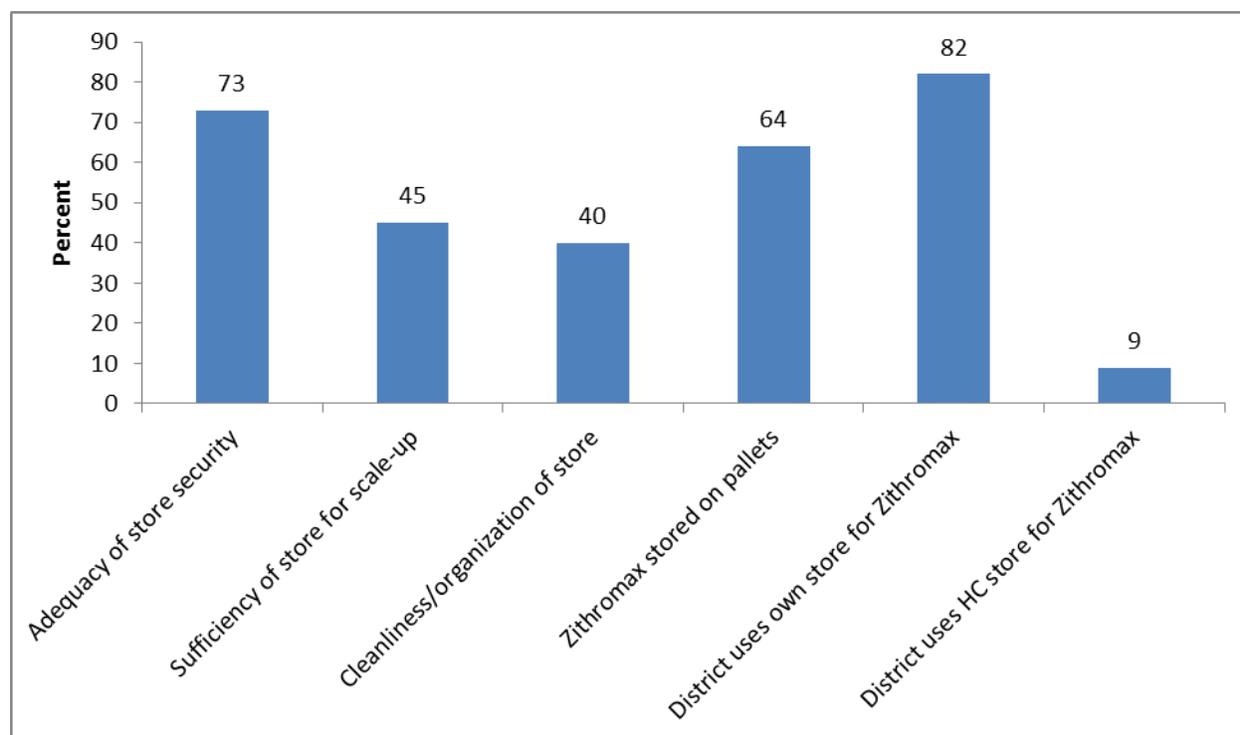
### ***Port Clearance of Zithromax***

According to the MOU signed between ITI and the FMOH, the FMOH is the official recipient of Zithromax donated by Pfizer for mass distribution for the control of trachoma. ITI is responsible for working with Pfizer to ensure the approved quantities of Zithromax tablets and pediatric oral suspension are shipped to the consignee, which is the FMOH. Pfizer is responsible for ensuring all the required documents for clearance are provided to the consignee in advance to avoid delays in clearance. PFSA is the responsible body that clears and stores all donated Zithromax. PFSA has a dedicated unit within its structure that is responsible for clearing all shipments for its own and FMOH's consignments, as required. The FMOH is responsible for providing the necessary letters and fees for duty-free clearance and covering other associated fees of PFSA. Except in events of delayed or incomplete clearance documents, the assessment team was informed that the clearance is smooth, and demurrage fees are extremely rare. The clearance unit does not face any challenges in clearing goods on time if all the shipping documents are received as required. PFSA uses its own fleet of trucks or third-party dependable transport agents to transport cleared Zithromax from the airport to the warehouses. Past experiences of delays in clearing sea shipments of Zithromax through the FMOH has given way to efficient clearance by PFSA.

### ***Storage of Zithromax***

PFSA currently has 17 modular warehouses located throughout the country. The latest is a 5,000-square-meter modern prefab (warehouse-in-a-box type) structure nearing completion in its complex central location in Addis. The ultimate plan is to reach to 25 storage hubs located geographically in zones to deliver products directly to health facilities. For Zithromax PFSA uses two of its rented warehouses at Lebu in the outskirts of Addis. These stores at Lebu are secure, spacious, and well maintained, with a computerized and centrally linked virtual bin card system. These stores also carry other PFSA products and other FMOH program products. The picture shows one of the Lebu stores of PFSA used for Zithromax storage. The store is well organized,

and Zithromax was observed to be stacked on pallets like other pharmaceuticals in the warehouse.



**Figure 8. Storage conditions in districts**

Security at district stores is modestly adequate with 73 percent of the districts claiming to have a secure store (see figure 8). Only 45 percent of the districts said they have adequate storage structure for the anticipated scale-up. Although Zithromax is kept for a maximum of two weeks before being sent out for mass administration, even the short holding period can be a security concern that needs immediate attention. The concerned partners and the FMOH have to look at

alternative temporary storage options to address these challenges. The use of PFSA hubs and adjoining HC stores can be considered. Forty percent of visited district stores are clean and organized, but the majority of 60 percent do not meet basic standards of medicine storage. Sixty-four percent of the districts use pallets to stack medicine cartons, and the others put the cartons directly on the floor, which can affect the stability and quality of the medicines stored if kept in such conditions for long. As witnessed in Butajira store managed by GTM, improvised local materials can be used as pallets to store medicine cartons to protect them against adverse storage conditions. Except GTM, districts use their own available stores, and only 9 percent of the districts use the adjoining HC store. The use of the HC store, if appropriate, is an option to tackle the problem faced by districts. The following pictures show a well-organized dispensing pharmacy and a store for Zithromax at GTM in Butajira town.



### ***Distribution of Zithromax***

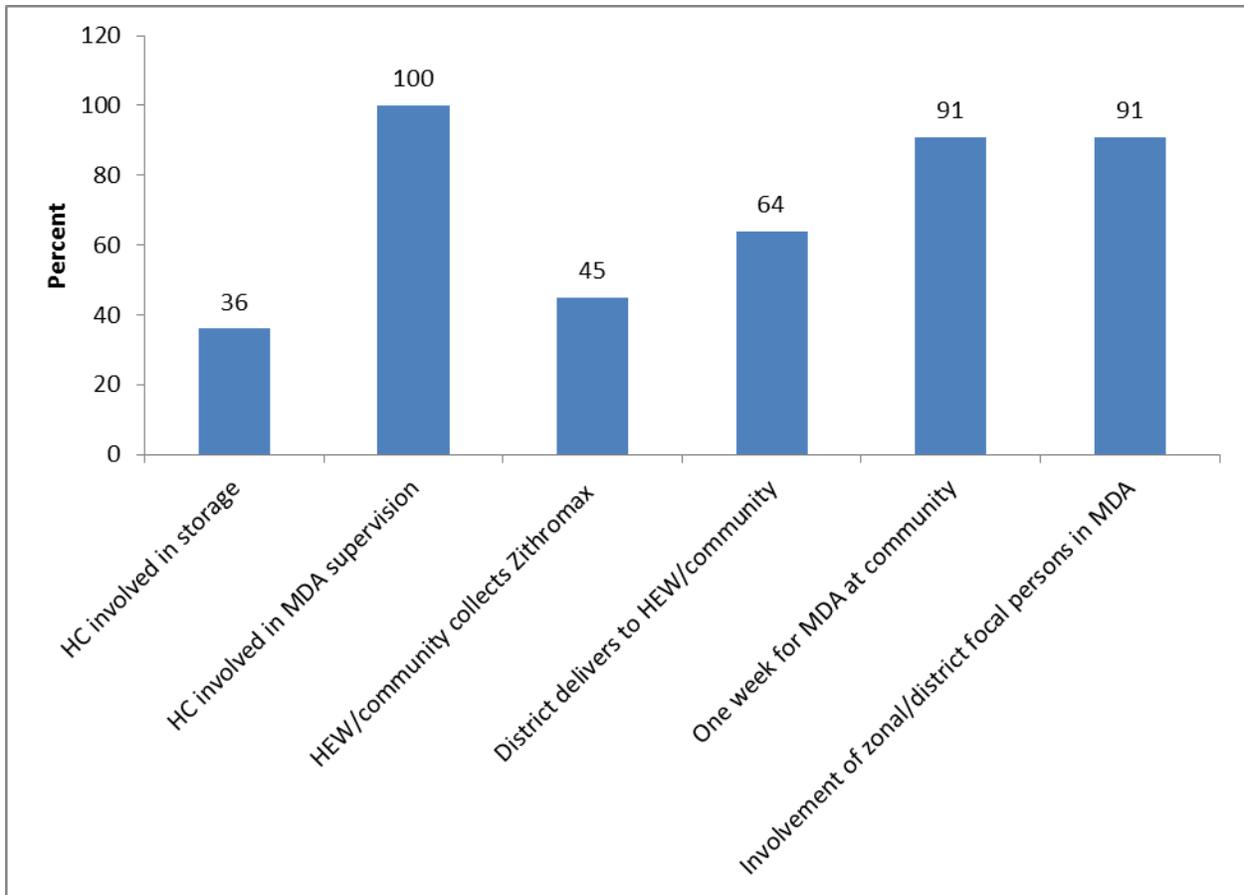
PFSA issues donated Zithromax in accordance with FMOH-approved quantities to partners to distribute Zithromax for mass administration in the approved districts. The quantity to be approved is based on number of persons to be treated as provided by the respective districts. In the majority of situations, the actual calculation of the quantities to be requested is done by the partners. The partners submit their request to ITI/Ethiopia, which checks against previous issues and distributions. The partner request is submitted to the FMOH. The FMOH approves the requested quantity that PFSA issues to the partner. The partner carries the approved request to PFSA where the order is filled by the store keeper at Lebu. The partner uses its own transport to take the consignment to its destination. Most of the partners directly take it to the target districts, except GTM, which stores the consignment at its store in Butajira in Gurage Zone of SNNPR and Zwai in Oromia Region, about two hours outside Addis Ababa.



Hawzein wereda store (exterior and interior views) with bin cards and proper storage

Distribution from the district to the campaign sites is mostly done by (a) the partners, or (b) by the districts themselves using their own transport, or (c) by HEWs who come and collect from districts. Once in the communities, the HEWs take charge of the Zithromax. During the mass distribution, in most instances Zithromax is kept at the health post of the respective HEWs or returned to the district or partner store until the next day of mass distribution. Unused Zithromax is collected back by the district and kept in the district store. GTM, which conducts distribution one district at a time, uses the unused Zithromax in the next district in line for mass distribution, ultimately keeping the ending unused balance at its stores in Butajira and Zwai.

The assessment findings on HC involvement and distribution mechanism are shown in figure 9.



**Figure 9. HC involvement and distribution mechanism for Zithromax**

Only 36 percent of the districts assessed use the HC store for Zithromax; the rest use their own stores. Because HCs have pharmacy professionals who can better manage medicines, using HC facilities is advisable as long as the HCs have the appropriate facility. HC, zonal, and district staff are fully involved in MDA campaigns in their respective catchment areas in supervision and distribution. Forty-five percent of HEWs collect the Zithromax allocated to their communities while the rest get it delivered by partners or districts. The maximum number of days it takes to complete mass administration in a community is one week, as stated by 91 percent of the districts assessed. The MDAs are primarily led by the HEWs who are the health focal persons of the communities. These HEWs are supported by Health Development Army members and volunteers in mobilizing communities and supporting the registration, conducting height measurement, and conducting the process in an organized manner. The HEWs conduct house-to-house distribution for persons who miss treatment for various reasons so that the target of at least 85 percent treatment is achieved.

### **MDAs Using HEWs**

Mass drug administration takes the form of bringing the people to be treated to a central place, such as a school, a religious facility, or a market place, and is managed by the HEWs in collaboration with Development Army members and other volunteers. Zonal, district, and HC

staff provide supervisory support. The HEW structure is a creative and sustainable means of achieving better coverage and dealing with persons who miss their treatment because they can be treated after the campaign is completed. More than 38,000 HEWs with the support of Health Development Army members in every community makes mass or house-to-house distribution dependable and sustainable.



Gabriel Daniel interviewing an HEW at health post in Zuwai district during the assessment

It was observed that the HEWs do not keep the community register used during the MDA, which is taken away by the partner for aggregating data for reporting. This practice can be improved by either keeping a copy or returning the community register to the HEWs. The HEWs are responsible for—

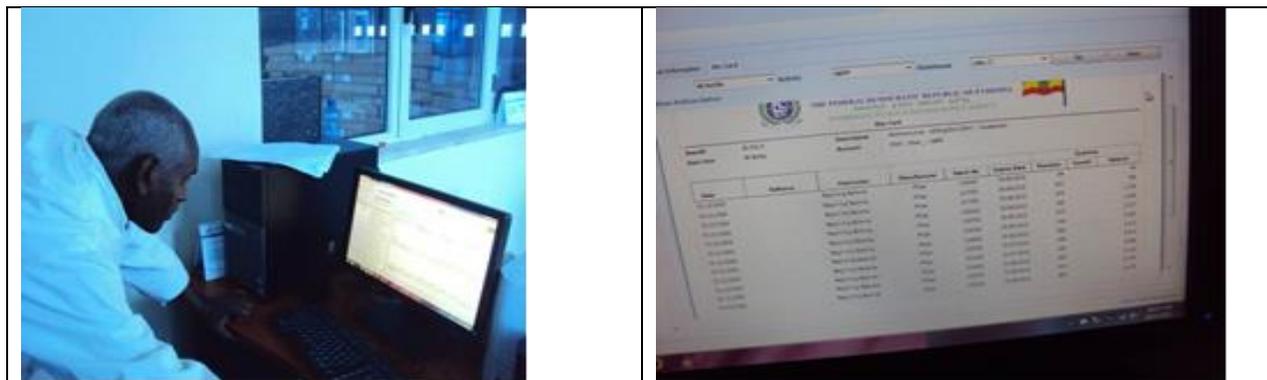
- Mobilizing and sensitizing the community
- Promoting health education and personal and environmental hygiene
- Treating enrolled eligible persons
- Identifying SAEs and referring the people affected to the health facilities
- Compiling treatment data and accounting for the medicines, returning drug balances and registers to the nearest health facility after MDA

Supervisors ensure that the activities are carried out according to the program requirements.

### ***Information System, Record Keeping, and Reporting***

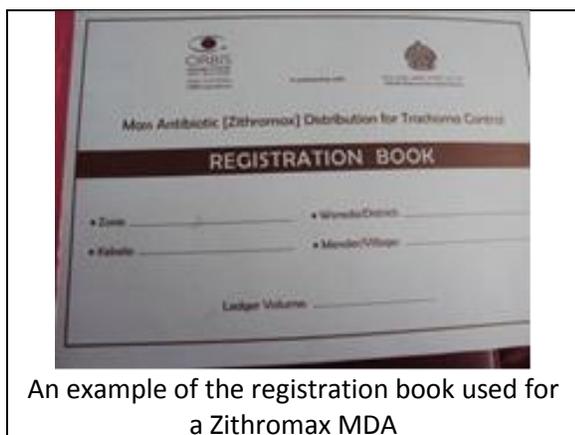
Records for clearing, receiving, storing, and issuing of Zithromax at PFSA follow the standard practice used for all other products. A goods receiving voucher is used to confirm receipt of the consigned shipment, and a copy is sent to ITI/Ethiopia ascertaining the same. Once Zithromax is received by PFSA, stock cards and bin cards are established. The warehouse that carries the Zithromax inventory has a virtual bin card that is electronically linked to the central information

unit of PFSA. PFSA has an integrated pharmaceutical logistics system used in all health facilities served by PFSA.



PFSA automated inventory control system at Lebu store where Zithromax is stored

The IPLS is a comprehensive stock management tool that is used for ordering, issuing, and receiving products and features stock status information such as balance on hand, monthly consumption rate, expiry information and the like. All Zithromax issue by PFSA is to partners. Partners make requests to the FMOH through the ITI/Ethiopia office. The FMOH approves the request and instructs PFSA in writing to issue the approved quantity to the delegated partner representative. The partner acknowledges receipt and delivers the shipment to the district for which the supply is destined. The partner transfers the shipment to the district using the official government form (called models). Once Zithromax is delivered to the district, the partner submits a copy of the signed receipt form to PFSA to confirm that the shipment has been delivered to the district. Although the district is expected to enter the information into stock card and bin card, this is not practiced in all the districts. When the district issues Zithromax for the campaign, issuing is done using the official government form, and the HEWs acknowledge receipt by completing the official receiving form. Since the HEWs do not store Zithromax during the campaign, stock or bin cards are not used.



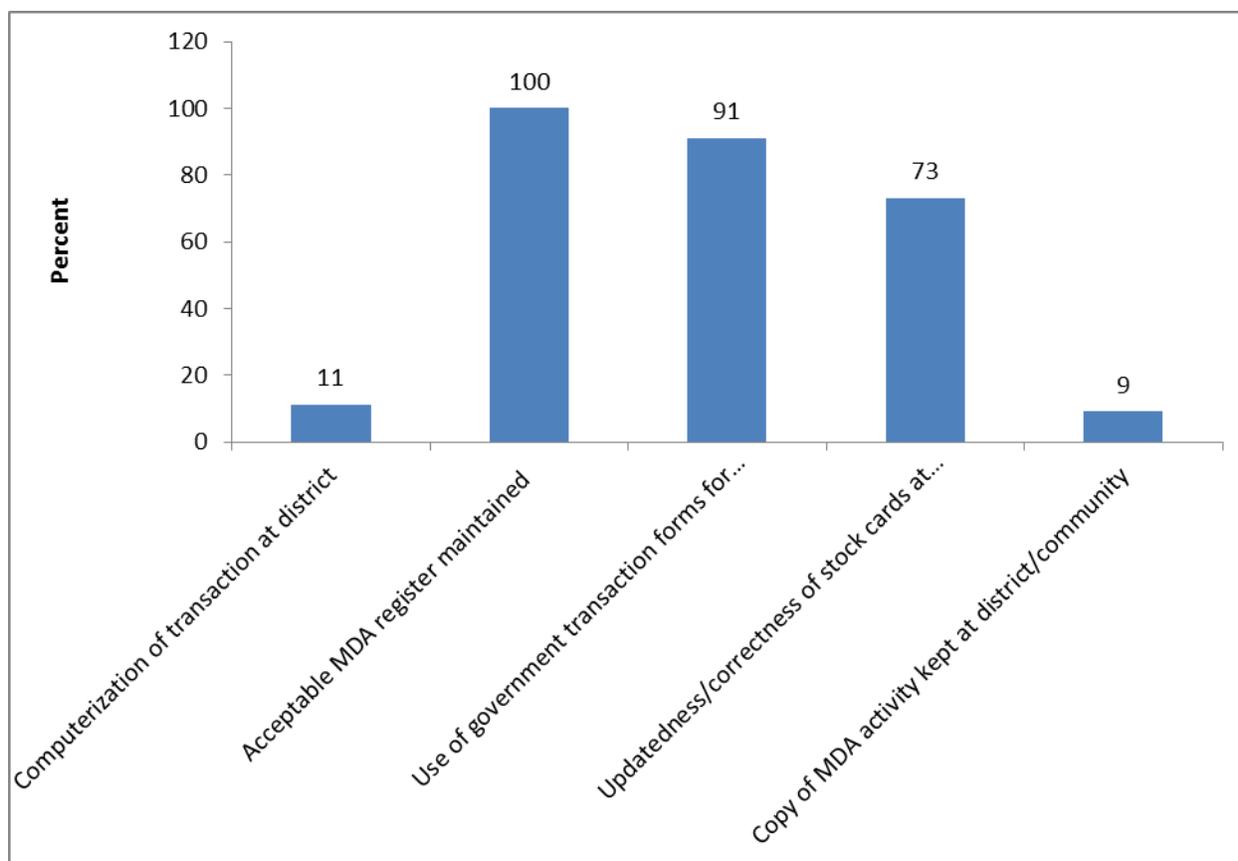
An example of the registration book used for a Zithromax MDA

The HEWs have a register that is provided by the partner. Each register has 50 pages, and a page is used for one household. Details in the register include names, ages, gender, height, doses administered, and year. The same household page is used for three to five years to ensure annual treatment is followed through. Some of the registers are pre-printed whereas others are manually prepared. Although registers are used in all the districts, the registers are not standardized. It is recommended that all registers be standardized or harmonized and be coordinated by the FMOH.

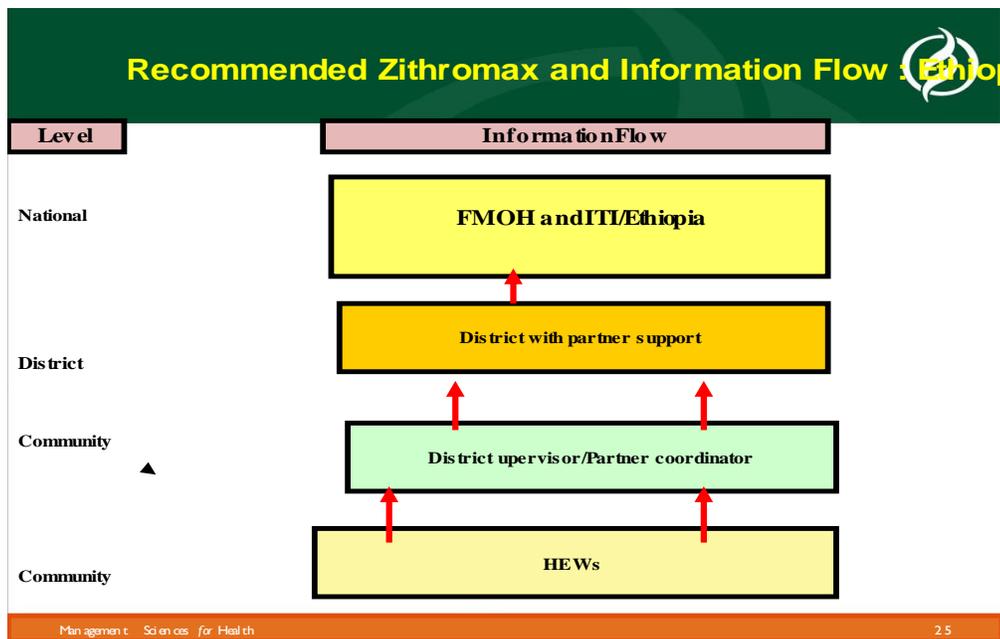
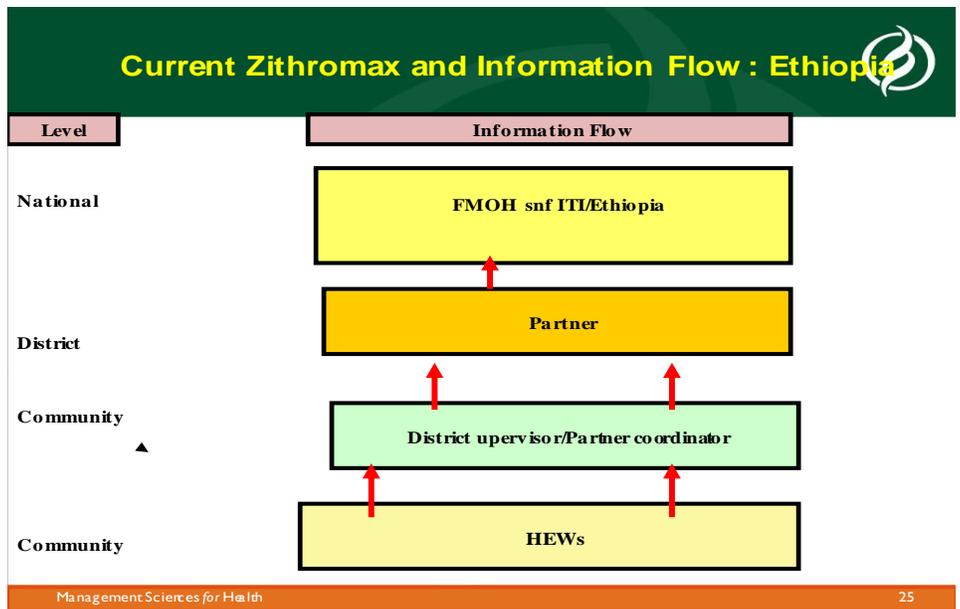
Despite such a systematic information system base, about half the visited districts showed a weak logistics management information system in practice. The use of bin cards or stock cards

for recording transactions and documenting balances, expiry, and batch numbers is not widely applied or not updated regularly. Without such tools, it is impossible to know stock levels and make decisions for redistribution. No specific SOPs apply to the management of Zithromax. The presence of such an SOP could have created uniformity of procedures and processes in registration and reporting.

As can be seen in figure 10, information on Zithromax management is computerized in only 11 percent of the districts. The use of government forms is consistent for issuing and receiving of Zithromax through the whole Zithromax supply chain. Seventy-three percent of the districts that use stock or bin cards are reported to maintain accuracy and updated entries and transactions. The major weakness observed is that MDA registers are not kept at community or district level. Ninety-one percent of the districts report that partners keep the registers, leaving no traceability or continuity and ownership at the beneficiary level.



**Figure 10. Zithromax management records**



**Figure 11. Current and recommended Zithromax information flow**

As seen from figure 11, the current practice of information flow depends on partners, who collect Zithromax stock and treatment information on behalf of districts, aggregate the information, and report to ITI/Ethiopia. This system relies on the resources of partners and does not build sustainability and ownership by districts. The recommended practice is for the information system to follow the IPLS and reporting of PFSA and FMOH, where the partners can assist in making available tools, training, mentoring, and data quality assurance.

## Inventory of Stock on Hand

As shown in table 3, of the 11 districts assessed, inventory was conducted in only 6 because of time constraints. Validation of stock card record with physical count was done in only 4 districts.

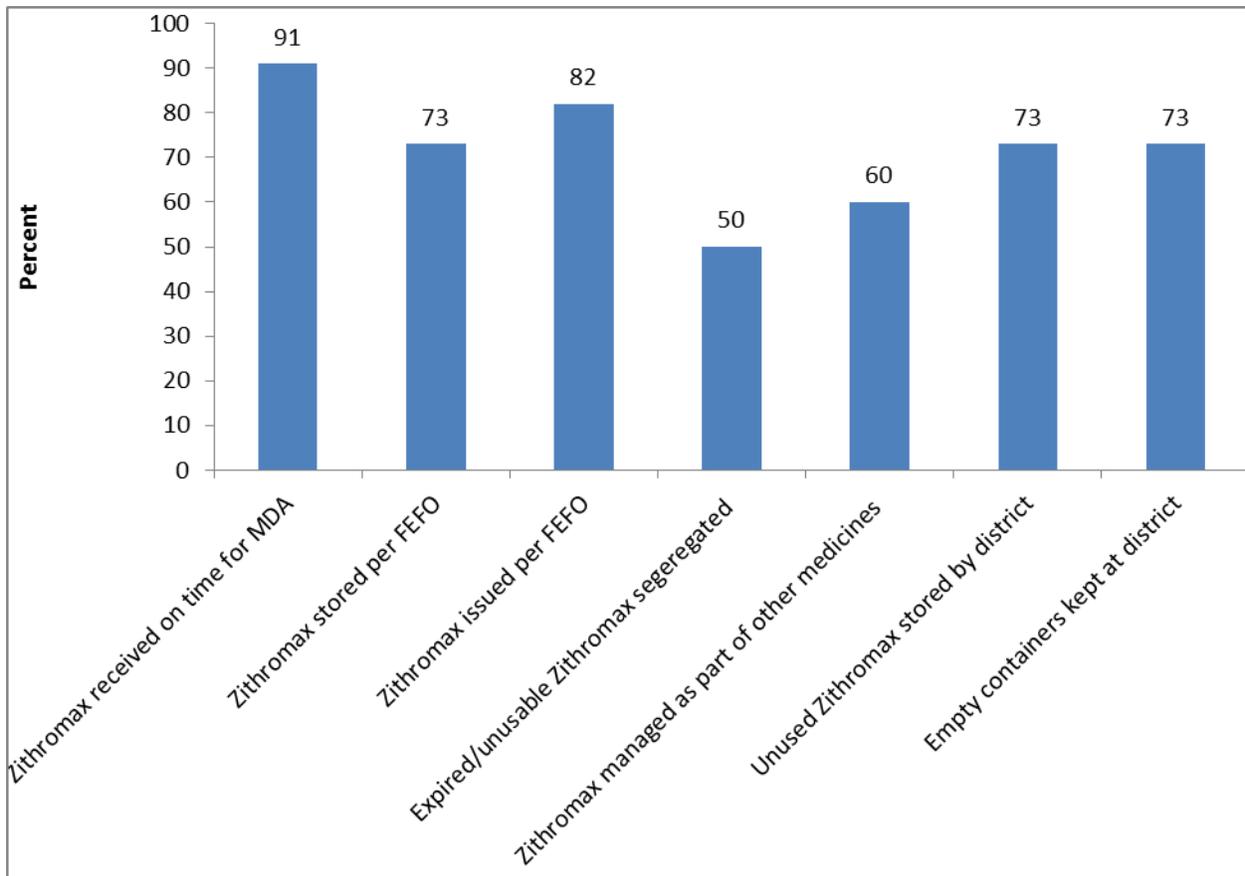
**Table 3. Inventory of Stock on Hand**

Inventory description	District 1	District 2	District 3	District 4	District 5	District 6
Starting stock	462,240	468,000	543,00	672,500	259,290	610,500
Number of persons treated	90,159	139,697	150,091	168,364	78,532	185,154
Quantity distributed	305,320	460,457	Na	537,500	19,200	610,500
Balance on hand	1,890	3,789	51,500	37,500	11,318	0
Returned to source/district	156,330	3,500	—	91,000	11,678	7,500
Transferred to other districts	—	—	—	—	—	—
Discrepancy between number of persons treated and quantity distributed	3%	6%	—	9%	—	6%
Discrepancy between opening balance and total quantity (distributed + on hand + returned)	0.3%	0%	—	1%	6%	1%
Quantity expired	—	—	—	—	—	—
Stock card balance	—	3,789	25,500	46,500	11,318	—
Physical count	—	3,789	37,302	46,500	11,237	—
Discrepancy/variance between recorded quantity and physical count	—	0	12,302 (+)	0	81 (-)	—

Note: — No data available.

Although the inventory and validation was incomplete given the short time the assessment team had to conduct the extensive exercise of field work, it is worth appreciating the presence of a functioning system that documents the described inventory data elements. Analysis of the data in table 3 for discrepancies and variances shows that the differences are not significant. The stock card balance and physical count for District 3 shows a significant difference, with the physical count showing a higher figure. Although there is always room for improving inventory control

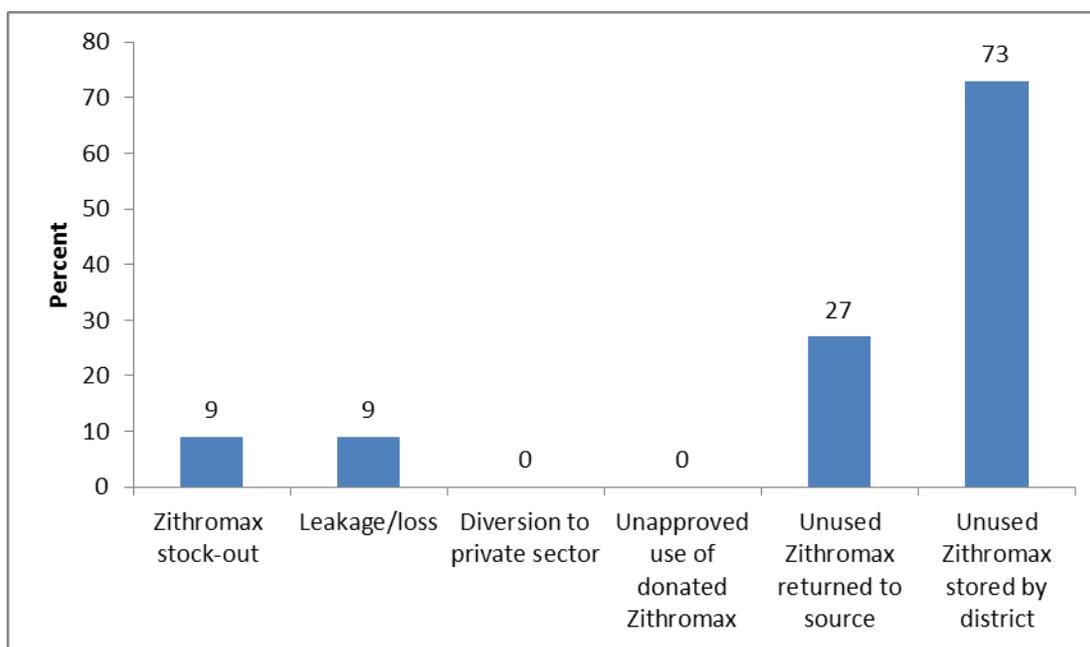
and accurate recording, the general conclusion from this exercise is that the districts did not manifest significant discrepancies that justify a red flag.



**Figure 12. Logistics management of Zithromax at district level**

The assessment of the districts showed that Zithromax was received on time for the campaign, and first-expiry, first-out (FEFO) management is practiced during storage and issue in most districts (figure 12). Expired medicines are segregated and stored away from usable stock in only 50 percent of the assessed districts.

Keeping expired products with active usable products runs the risk of mistaken use of the expired product, which also competes for storage space with active products. It is recommended that expired products are stored safely in a separate place. It is also recommended that expired Zithromax is disposed following the national disposal guideline expeditiously by following the guidance of the region/zone or district. Seventy-three percent of the districts assessed stated that unused Zithromax that is returned after campaigns is kept at district stores. As stated earlier, the district stores have a weak inventory management system and inadequate and less than optimal storage conditions. A similar percentage of the districts stores empty containers after campaigns. The guidance on what to do with empty containers lacks clarity. These containers are taking a lot of usable space at districts. It is recommended that unused Zithromax is returned to PFSA so that proper storage conditions are maintained before these products are reused. Clear guideline should be provided on the fate of empty containers. It is suggested by persons interviewed that with proper defacing they can be used for other purposes by health facilities, HEWs, and community members.



**Figure 13. Zithromax inventory control findings at district level**

The district assessment found out that Zithromax stock-out and loss or pilferage was extremely low at 9 percent (figure 13). Diversion to the commercial sector and unapproved use outside MDA is nonexistent. There is a stringent regulatory and inspection system that ensures the use of

antibiotics only with prescriptions, making use of Zithromax in illicit ways very unlikely. Isolated instances of loss during transport were reported a couple of years ago, and the case has been in court.

***National Stock-on-Hand Estimate Based on Information Available at the Central, Regional, and Health District Levels***

Although stock inventory was conducted in selected districts, such data were not considered to be valuable because they do not carry significance in that the quantity stored at districts is insignificant. Most of the stock has been used, and the quantity initially distributed is based on the number of persons projected to be treated. The districts are used as interim storage facilities and are not meant to keep stock for long periods. The only stock that may be found there is the stock returned after MDAs, which usually is low.

Zithromax is stored in two separate PFSA warehouses in the environs of Addis Ababa. The assessment team has witnessed acceptable storage of the stock in one of the stores but could not visit the other store because the store keeper was engaged in another task at the time. Inventory was not conducted because the visit of the assessment team coincided with the annual audit and inventory being conducted by PFSA for all its warehouses.

***Data on Inventory, Lot Numbers, and Expiry Dates of Zithromax, When Available***

Same as above.

**Technical Resources Drawn upon by FMOH, PFSA, and RHBs for Supply Chain Management Training and Technical Assistance**

Except during mass campaigns, no trainings are provided to regional, zonal, or district personnel. During these orientations, the pharmacy personnel are not included, making use of their supply chain and pharmaceutical services unavailable for Zithromax management.

**Analysis of Current Buffer Stock Policy and Recommendation for Modifications**

There is no policy or practice related to requesting and maintaining buffer stock. The purpose of buffer stock is to ensure uninterrupted supply and cater for unforeseen situations, delayed shipments, losses, expiries, damage, or increased use caused by justifiable reasons such as seasonality that brings residents back to their communities.

**Progress Made in Relation to Recommendations Cited in 2009 Supply Chain Assessment Report for Ethiopia, Conducted by John Snow, Inc.**

The team learned that because no organized system exists for following up on recommendations made and the report was not shared with the appropriate office, most of the recommendations

were not implemented. The responses under each of the recommendations will therefore be status appraisal. The relevant and still valid recommendations are considered as part of the current recommendations.

1. Design and implement a single logistics system for all implementing partners, including common LMIS [logistics management information system], standard inventory control procedures, and procedures for storage and distribution.  
*This recommendation was not implemented. PFSA has adopted a logistics master plan that guides the practice of the pharmaceutical management system. It includes an IPLS for order, issue, and receipt transactions at all levels. There are standard pharmaceutical procedures for inventory control, storage, distribution, disposal, etc. The existing system can easily be adapted to Zithromax.*
2. Revise LMIS forms and procedures to enhance accuracy and accountability.  
*LMIS forms are standardized and can be adapted to Zithromax.*
3. Consider establishing MOUs with implementing partners.  
*The assessment found that partners have signed MOUs with RHBs.*
4. Increase ITI's central level access to accurate and timely logistics information, and develop data management tools to aggregate, analyze, and use data for decision making.  
*Data from districts and partners needs to be aggregated. No system is in place to accomplish this. Transaction and stock status information used to be submitted by PFSA to the FMOH, but there was no centralized mechanism to use or share the information. ITI had to resort to informal methods to get such information. The assessment team has learned that PFSA will produce monthly report on Zithromax transaction and stock status that will be submitted to the NTD/Trachoma unit, which will then be shared with ITI.*
5. For the Carter Center, adjust current inventory control procedures—including the recalculation of order quantities and management of buffer stock—to avoid stock imbalances.  
*Because this recommendation applies to other partners also, it will be necessary to produce an SOP to address such issues and orient/train relevant personnel of the Ministry and partners to adhere to SOPs.*
6. Require quarterly physical inventory at wereda storage facilities.  
*Currently this is not being observed. The NTD/Trachoma unit of the FMOH needs to require all facilities that hold Zithromax at their stores to provide a quarterly stock status report including expiry dates and batch numbers.*
7. Provide performance improvement opportunities for staff at all levels in Zithromax management.  
*Deficient capacity building in Zithromax management exists at all levels. The Zithromax Program Manager's Guide was widely absent at partners and districts. The only training provided is for campaign-involved personnel, and this excludes pharmacy personnel. It is necessary to develop materials and plan regular training in Zithromax management for all*

*personnel with the potential to get involved in trachoma control, including pharmacy personnel at various levels.*

8. Develop detailed guidelines outlining recommended and required procedures for Zithromax management.  
*No SOP exists for Zithromax management. It is important to develop such an SOP and make it widely available to enhance the upcoming scale-up.*
9. Improve forecasting accuracy and document forecasting methodologies and assumptions.  
*The current practice of quantification, forecasting, and supply planning is done in ad hoc manner and does not consider different assumptions that affect optimal stock. The process of quantification, forecasting, and supply planning needs to be guided by proven methods and involve various stakeholders. The pharmaceutical management system has developed guidelines that can easily be adapted to Zithromax quantification and forecasting.*
10. Involve partners in quantification to improve accuracy and to ensure requirements are included in long-term procurement plans.  
*As above.*
11. Determine resources required to strengthen storage and distribution.  
*Storage and distribution practices can benefit from resources that can alleviate the existing space and storage condition challenges. The use of the PFSA hubs that are closer to districts can contribute to partially addressing this problem. In addition to bringing Zithromax closer to the districts, unused Zithromax can be stored at the hubs, where storage conditions are optimal.*

## **Recommendations for Addressing Supply Chain Management Weaknesses or Gaps**

Refer to Executive Summary.

## **Plan of Action**

The assessment team is planning to conduct a postassessment and report dissemination workshop in Ethiopia to bring all key stakeholders and partners together to discuss the findings and recommendations and to share experiences and best practices as a springboard for the 2014 scale-up of Zithromax distribution.

## **Quality Assurance and Medicine Safety Monitoring (Pharmacovigilance)**

Ethiopia has developed a national pharmaceutical waste disposal guideline. Although large quantities of expired Zithromax do not exist, the assessment showed quite an accumulation of empty Zithromax containers at district stores. The absence of clear guideline on disposal or reuse

of empty containers and their storage at the facilities was mentioned by several interviewed persons as a challenge.

A national guideline governs pharmacovigilance, containment of AMR, ADR reporting, and disposal of expired and unusable pharmaceutical products. Although the assessment did not find SAEs as a reported problem, other ADRs are reported to be commonly encountered. At times because of weak public awareness and community education, instances of low coverage were reported. The ADRs experienced are not documented on any of the available forms and hence do not get attention and follow-up. ADR monitoring and reporting are part of the training provided to distributors. The interviews at central and district levels indicate the number of persons experiencing ADRs is insignificant, and if it exists it is mild. There were reports where people have refused to receive treatment because of unfounded rumors, which have been corrected with public health education.

The FMHACA is the regulatory arm of the government that can effectively be used in providing guidance and support in the areas of disposal of expired and unusable products, pharmacovigilance/ADR reporting, and regular inspections of private outlets for evidence of diversion of donated products.

All donated NTD medicines are sourced from the parent manufacturers, which makes quality issues less of a concern. However, some concern may exist about the downstream quality of NTD medicines because they come as loose pills and are distributed from containers. The nature of the mass administration does not ensure that the container lid is placed tightly on the container between uses because it is used continuously. Mass administrations are conducted mostly outdoors, and the chances of exposure of the medicines to humidity, heat, dust, and other unhygienic situations are great.

At the end of the mass distribution, the medicines are kept with the distributors for some time before being sent back to the higher level. Once at the higher level, these opened medicines are kept until the next round of distribution. Ensuring stability, safety, and effectiveness of these remaining medicines is difficult. Reports indicated instances when transfer of returned balances to other districts that faced shortages were not accepted because of suspicion that the safety of an already opened drug cannot be guaranteed. Regarding package sizes, lessons that could be learned from Merck is that at the start of the Mectizan MDA for onchocerciasis, Mectizan was packed in aluminum foil packs that can be cut according to the required doses at the time of distribution. This practice has the advantage of ease of counting for strong inventory control; protecting the medicine from exposure to humidity, dust and unhygienic conditions; and contributing to good dispensing and handling practices. The downside of the multipill bottles is the challenge in counting balances to validate reported quantities against actual counts, which would be easier to do if they were foils.

## ANNEX 1: KEY PERSONS MET

<b>Name</b>	<b>Title</b>	<b>Organization/Affiliation</b>
Dr. Kebede Worku	State Minister of Health	FMOH
Mr. Oumar Shafi	NTD team leader	FMOH
Mr. Gabremaskal Habtemariam	Advisor, NBCP	FMOH
Ms. Genet Kiflu	Trachoma Focal Person	FMOH
Mr. Noah Kafumbe	ITI Supply Manager	ITI/US
Dr. Teshome Gebre	ITI Regional Director, Africa	ITI/Eth
Dr. Menbere Alemu	ITI Country Representative	ITI/Eth
Mr. Girma Tadesse	ITI Logistics Officer	ITI/Eth
Dr. Wondu Alemayehu	Consultant	Berhan PH & Eye Care Consultancy,
Dr. Zerihun Tadesse	Country Representative	The Carter Center, Ethiopia
Dr.ayehu Sisay	Country Representative	Orbis, Ethiopia
Mr. Ayele Atlabachew	Project Officer	World Vision, Ethiopia
Mr. Teshome Tulu	Manager	Girarbet Blindness Hospital, Butajira
Mr. Tesfaye Tadele	Trachoma Field Coordinator	Girarbet Blindness Hospital, Butajira
Mr. Ahmed Ababajobir	Country Representative	Fred Hollows Foundation, Ethiopia
Mr. Birhanu Bero	Project Officer	Fred Hollows Foundation, Ethiopia
Mr. Yemanebirhan adesse	Deputy Director General	PFSA
Ms. Safia Nuru	Distribution Team Leader	PFSA
Mr. Mulugetta Getaneh	Clearance Officer	PFSA
Mr. Wonde Alemu	Planning and Program Team Leader	FMHACA
Mr. Solomon Gadissa	NTD adviser	Oromia RHB/Global Health
Dr. Negussu Mekonnen	Country Representative	MSH, Ethiopia
Mr. Hailu Tadeg	Deputy COP	SIAPS/MSH, Ethiopia
Mr. Getchew Ayalew	Regional Coordinator	SIAPS/MSH, Ethiopia
Mr. Getahun Sisay	Senior Technical Adviser	SIAPS/MSH, Bahrdar, Amhara
Mr. Mulugetta Asfaw	Senior Technical Adviser	SIAPS/MSH, Awassa, SNNPR
Mr. Meressa Weldegebriel	Senior Technical Adviser	SIAPS/MSH, Mekele, Tigray
Mr. Fikadu Deme	Senior Technical Adviser	SIAPS/MSH, Addis Ababa, Oromia

## ANNEX 2: DISTRICT (WEREDA) CHECKLIST: DONATED ZITHROMAX SUPPLY CHAIN/LOGISTICS MANAGEMENT

ONE OF FIVE QUESTIONNAIRES USED IN THE ZITHROMAX ASSESSMENT OF MSH/ITI (QUESTIONNAIRES WERE DEVELOPED FOR PFSA, REGIONS, DISTRICTS, KEBELES, AND PARTNERS)

<b>Country:</b>	<b>Date of Interview:</b>
<b>Region:</b>	
<b>Wereda:</b>	
<b>Interviewee (must have worked at the facility for at least a year and be familiar with Zithromax management) :</b>	
<b>Contact Number of Interviewee:</b>	
<b>Interviewer:</b>	

1. There is an NTD focal person:	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. There is a trachoma/Zithromax focal person	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Are NTD or trachoma focal person(s) involved in wereda campaign?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Is Zithromax management integrated with other NTDs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5. Are other NTD drugs in addition to Zithromax stored/managed by the wereda store?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Is there a copy of the Zithromax Program Manager's Guide at the wereda?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7. Are staff trained in Zithromax management, including storage, record keeping, and reporting?	Wereda NTD/Trachoma Wereda pharmacy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
8. Who provides Zithromax tablet and pediatric oral suspension to the wereda?	<input type="checkbox"/> Region <input type="checkbox"/> Zone <input type="checkbox"/> Partner (specify) <input type="checkbox"/> Other (specify)	
9. Who provides tetracycline eye ointment to the wereda?	<input type="checkbox"/> Region <input type="checkbox"/> Zone <input type="checkbox"/> Partner (specify) <input type="checkbox"/> Other (specify)	

10. Do you have (have you seen) a copy of your wereda's Zithromax issue document from PFSA?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Was there any discrepancy/difference between the amount issued by PFSA and the amount received?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Which partner(s) supports Zithromax distribution in the wereda?	
13. What forms/types of support are provided?	<input type="checkbox"/> Transport for delivering Zithromax <input type="checkbox"/> Allowance/transport for persons involved in the campaign <input type="checkbox"/> Training in Zithromax management, including record keeping <input type="checkbox"/> Stationery/registers <input type="checkbox"/> Preparation of postcampaign report <input type="checkbox"/> Other (specify)
14. When was the last campaign in the wereda?	
15. When is the next campaign in the wereda?	
16. How many kebeles were served in the immediate past campaign?	
17. How is Zithromax distribution conducted in the wereda?	<input type="checkbox"/> Alone (not integrated/combined with other treatments) <input type="checkbox"/> With malaria treatment at the same time (MalTra) <input type="checkbox"/> With other NTDs at the same time (specify _____) <input type="checkbox"/> With other NTDs but on different days (specify treatments and time frame _____)
18. How many days does it take to complete Zithromax distribution in the wereda?	<input type="checkbox"/> One week <input type="checkbox"/> 2–3 weeks <input type="checkbox"/> 3–6 weeks <input type="checkbox"/> Other specify _____
19. Have you experienced stock-out of Zithromax during 2013?  If yes, how many days? What action was taken to address the stock-out?	<input type="checkbox"/> Yes <input type="checkbox"/> No
20. Was there any leakage/theft/pilferage of Zithromax in the last two years?  If yes, what and how much?  If yes, what action was taken?	<input type="checkbox"/> Yes <input type="checkbox"/> No
21. What was the average time in days between receipt in district of Zithromax and first delivery for the campaign?	
22. Was Zithromax received on time for the campaign?	<input type="checkbox"/> Yes <input type="checkbox"/> No

23. Is donated Zithromax also used for infections other than trachoma in the wereda?	<input type="checkbox"/> Yes <input type="checkbox"/> No
24. Is Zithromax given to patients free of charge?	<input type="checkbox"/> Yes <input type="checkbox"/> No
25. Have you come across donated Zithromax being sold in the private sector (pharmacies, etc.)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
26. Is the wereda involved in determining the amount of Zithromax to be ordered?	<input type="checkbox"/> Yes <input type="checkbox"/> No
27. How is Zithromax delivered to the wereda?	<input type="checkbox"/> Wereda uses its own or rented transport <input type="checkbox"/> Partner delivers <input type="checkbox"/> Other (specify)
28. How is Zithromax delivered to the kebele or community for the campaign?	<input type="checkbox"/> Wereda uses its own or rented transport <input type="checkbox"/> Partner delivers <input type="checkbox"/> HEW/community comes to collect <input type="checkbox"/> Other (specify)
29. Where is Zithromax stored at the wereda?	<input type="checkbox"/> Wereda uses its own store <input type="checkbox"/> Wereda uses health center store <input type="checkbox"/> Partner's store <input type="checkbox"/> Other (specify)
30. Who is the custodian of Zithromax at the wereda?	
31. Are health centers involved in Zithromax/trachoma in the wereda?	<input type="checkbox"/> Not involved <input type="checkbox"/> Wereda uses health center store <input type="checkbox"/> Provide staff for supervision <input type="checkbox"/> Distribute Zithromax to kebeles/community <input type="checkbox"/> Other (specify)
32. Is all Zithromax <b>stored</b> according to first-expiry, first-out (FEFO) method? (Observe if practiced)	<input type="checkbox"/> Yes <input type="checkbox"/> No
33. Is all Zithromax <b>issued</b> according to first-expiry, first-out (FEFO) method? (Check if practiced)	<input type="checkbox"/> Yes <input type="checkbox"/> No
34. Who maintains Zithromax transaction records (receipt, issue, transfer, etc.) at the wereda? At the kebele?	
35. Who prepares Zithromax report on use and stock status in the wereda? In the kebele?	
36. Who approves Zithromax report on use and stock status in the wereda?	
37. What happens to Zithromax not used after a campaign?	<input type="checkbox"/> Returned to source/partner picks it up <input type="checkbox"/> Stored at wereda warehouse

38. What is the average time in days between completion of campaign and reporting? (Specify for MDAs and wereda.)	
39. Where are wereda MDA reports sent?	<input type="checkbox"/> Region <input type="checkbox"/> Zone <input type="checkbox"/> Partner <input type="checkbox"/> Other (specify)
40. Is passive treatment of trachoma (for patients diagnosed at facility level) conducted with donated Zithromax?	<input type="checkbox"/> Yes <input type="checkbox"/> No
41. What are the sources of Zithromax for clinic-based treatment?	
42. How far is the nearest PFSA store from the wereda?	
43. Is there adequate security at the wereda store (secure windows, doors, intact ceiling, etc.)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
44. Is the current store sufficient for Zithromax received for the current campaign?	<input type="checkbox"/> Yes <input type="checkbox"/> No
45. Is the current store sufficient for an anticipated doubling or tripling of Zithromax supply?	<input type="checkbox"/> Yes <input type="checkbox"/> No
46. If not sufficient, how do you plan to accommodate the scale-up?	
47. Are Zithromax boxes/cartons stored on the veranda or in other areas not dedicated for medicines?	<input type="checkbox"/> Yes <input type="checkbox"/> No
48. Is expired or other unusable Zithromax stored in a separate area (segregated from usable products)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
49. Is Zithromax in the store exposed to direct sunlight in the store?	<input type="checkbox"/> Yes <input type="checkbox"/> No
50. Is the store clean and free of rubbish?	<input type="checkbox"/> Yes <input type="checkbox"/> No
51. Are cartons/boxes of Zithromax stacked on pallets?	<input type="checkbox"/> Yes <input type="checkbox"/> No
52. Are cartons/boxes of Zithromax stacked at least 10 cm off the floor?	<input type="checkbox"/> Yes <input type="checkbox"/> No
53. Are cartons/boxes of Zithromax stacked at least 30 cm away from the walls and other stacks?	<input type="checkbox"/> Yes <input type="checkbox"/> No

54. Are cartons/boxes of Zithromax stacked no more than 2.5 meters high?	<input type="checkbox"/> Yes <input type="checkbox"/> No
55. Are medicines (including Zithromax) stored with items such as insecticides, chemicals, stationery, furniture, etc.?	<input type="checkbox"/> Yes <input type="checkbox"/> No
56. Have there been instances when Zithromax tablets or pediatric oral suspension has been received with shelf life less than six months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
57. Is Zithromax transaction computerized?	<input type="checkbox"/> Yes <input type="checkbox"/> No
58. Are records/registers maintained for each patient (e.g., by age, sex, dose administered, adverse reaction etc., during MDAs on <b>year-by-year basis</b> on the same register?  Check register	<input type="checkbox"/> Yes <input type="checkbox"/> No
59. When was the last inventory conducted in the wereda for Zithromax?	
60. Do you maintain stock card/bin card for Zithromax and tetracycline eye ointment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
61. Are additional types of Zithromax tools/forms/registers provided by the partner?  If yes, specify:	<input type="checkbox"/> Yes <input type="checkbox"/> No
62. Are stock cards/bin cards up to date for Zithromax and tetracycline eye ointment entries (receipt, issue, balance, expiry etc.)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
63. Are stock cards/bin cards correctly filled and accurate for Zithromax and tetracycline eye ointment entries?	<input type="checkbox"/> Yes <input type="checkbox"/> No
64. Are delivery vouchers used when receiving Zithromax and tetracycline eye ointment from supplier or partner delivering the product?	<input type="checkbox"/> Yes <input type="checkbox"/> No
65. Is delivery voucher signed and returned to supplier?	<input type="checkbox"/> Yes <input type="checkbox"/> No

66. Are all Zithromax and tetracycline eye ointment receipts and issues entered into appropriate government models?	<input type="checkbox"/> Yes <input type="checkbox"/> No
67. Have you come across quality problem with Zithromax®?  If yes specify the type of problem.	<input type="checkbox"/> Yes <input type="checkbox"/> No
68. How many serious adverse event (SAE) notification reports have been documented/sent at the end of the last campaign?  To whom?	
69. Is there a regional/zonal pharmacy professional involved in Zithromax management and support to the wereda?	<input type="checkbox"/> Yes <input type="checkbox"/> No
70. Is there a regular postcampaign review meeting of region/zone/wereda offices, partners, and other relevant persons?	<input type="checkbox"/> Yes <input type="checkbox"/> No
71. Is Zithromax managed as part of essential medicines by the wereda pharmacy department?	<input type="checkbox"/> Yes <input type="checkbox"/> No
72. Is there a disposal guideline for expired and obsolete medicines in the wereda?	<input type="checkbox"/> Yes <input type="checkbox"/> No
73. When was the last time expired/unsable Zithromax was disposed of?  If done, describe how the disposal was conducted?	
74. What is done with empty Zithromax containers (bottles, tins)?	Returned to the source? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Kept in the store? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Defaced before reuse/recycling? <input type="checkbox"/> Yes <input type="checkbox"/> No

75. Provide the information for the specified indicators for the last campaign.	Quantity carried forward from previous campaigns (specify unit)	Zithromax tablets	
		Pediatric oral suspension	
		Tetracycline eye ointment	
	Quantity newly received for current/immediate past campaign	Zithromax tablets	
		Pediatric oral suspension	
		Tetracycline eye ointment	
	<b>Total starting stock</b> (total of the two above) at the beginning of the campaign	Zithromax tablets	
		Pediatric oral suspension	
		Tetracycline eye ointment	
	Number of persons <b>treated</b> with	Zithromax tablets	
		Pediatric oral suspension	
		Tetracycline eye ointment	
	Number <b>distributed</b> (specify unit)	Zithromax tablets	
		Pediatric oral suspension	
Tetracycline eye ointment			
<b>Balance on hand</b> (specify unit)	Zithromax tablets		
	Pediatric oral suspension		
	Tetracycline eye ointment		
Number <b>returned</b> to source	Zithromax tablets		
	Pediatric oral suspension		
	Tetracycline eye ointment		

**Zithromax and Tetracycline Eye Ointment Inventory**

<b>Region</b>	
<b>Wereda</b>	
<b>Date</b>	

<b>Product</b>	<b>Unit</b>	<b>Stock on hand from Stock Card (only usable stock)</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b>Physical Count</b>	<b>Quantity Expired (On Hand)</b>	<b>Quantity of Unusable Stock (Damaged, Partially Used, Opened etc.)</b>	<b>Losses/ Adjustments</b>
<b>Zithromax Tablets</b>								
<b>Total Tablets</b>								
<b>Zithromax POS</b>								
<b>Total POS</b>								
<b>Tetracycline Eye Ointment</b>								
<b>Remarks</b>								

<b>Comments</b>
<b>Best Practices/Lessons Learned:</b>
<b>Other Observations/Comments:</b>
<b>Recommendations/Suggestions for improving the Zithromax management from Interviewed:</b>