Zithromax® Supply Chain Assessment Tool

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International Trachoma Initiative

Zithromax® Supply Chain Assessment Tool

(Excerpt)

Purpose

The Zithromax® Supply Chain Assessment Tool is designed to guide assessment team members through a series of interviews with key informants and to establish inspection procedures when conducting logistics field assessments. The protocol allows the assessment team to examine the readiness of the National Trachoma Control Program and the District- level health management structures to receive, manage, distribute and administer donated Zithromax® for mass drug administration. Pfizer, Inc. donates Zithromax® to trachoma-endemic countries in coordination with the International Trachoma Initiative (ITI). Due to the fact that the consignments of donated product are significantly large and of high value, a supply chain assessment helps identify functional areas of supply management that need strengthening prior to the arrival of a Zithromax® shipment.

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 _____

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., unusable) 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., <30ºC).			
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:

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