



Warehouse Standard Operating Procedures

Federal Directorate of Immunization

Ministry of National Health Services, Regulations and Coordination, Government of Pakistan



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Disclaimer

This publication was prepared by the U.S. Agency for International Development (USAID) funded, Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project, managed by Chemonics International Inc. The authors' views expressed in this publication do not necessarily reflect the views of the USAID or the United States Government.

USAID Pakistan Supply Chain Cooperation Standards and Policies can be found at: https://v.lmis.gov.pk/docs/pakistan-supplychain-sops

CONTENTS

ACRONYMS	vii
ACKNOWLEDGMENT	ix
PREFACE	xi
INTRODUCTION	1
1.0 RECEIPT PROCEDURE	2
2.0 STORAGE	11
3.0 ISSUE PROCEDURE	16
4.0 DISPOSAL	26
5.0 ANNEXURES	28

ACRONYMS

AWB Air Way Bill

BCG Bacillus Calmette-Guérin

CCM Cold chain monitoring

CR Cold room

FDI Federal Directorate of Immunization

FEFO First to-Expire, First Out

FR Freezer room

GHSC-PSM Global Health Supply Chain Program-Procurement and Supply Management

Hib Haemophilus Influenzae disease type b

ISO Organization for Standardization

ILR Ice-lined refrigerator

IRV Issue and Receipt Voucher

MDVP Multi-dose Vial Policy

MMR Measles, mumps, rubella

MoNHSR&C Ministry of National Health Services, Regulations & Coordination

OPV Oral polio vaccine
PAD Product Arrival Date

PAR Product Arrival Report
PCV Pneumococcal vaccine

SOP Standard operating procedure

TT Tetanus Toxoid vaccine

UN United Nations

USAID U.S. Agency for International Development

VAD Vaccine Arrival Date
VAR Vaccine Arrival Report

vLMIS Vaccine logistics management information system

VVM Vaccine vial monitor

WHO World Health Organization

WMS Warehouse Management System

ACKNOWLEDGMENT

Modernization of the central warehouse of Federal Directorate of Immunization (FDI), Ministry of National Health Services, Regulations, and Coordination, Islamabad has brought incredible results and has created the need for standardization to accelerate the pace of work. The scope and scale of work at the FDI warehouse in Islamabad have categorized it as the public institution for storing, managing, and distributing life-saving vaccines across the country. With the technical support of USAID funded Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project, the FDI has been able to develop standard operating procedures (SOPs) for managing day to day operational activities at the central warehouse.

The FDI highly appreciates the valuable support extended by USAID/Pakistan towards sustainable immunization supply chain system strengthening in the country. We thank Mr. Bradley Cronk, Director Health Office, USAID/Pakistan for his leadership in successfully strengthening, rehabilitating, and upgrading the FDI Warehouse in Islamabad to improve warehouse management system as per the international standards.

We also express our gratitude to Dr. Muhammad Tariq, Country Director, USAID GHSC-PSM project in Pakistan, for his leadership role; and his dedicated team for their effort and support in developing the *Warehouse Standard Operating Procedures*.

Dr. Muhammad Ahmed Kazi

Director General, Federal Directorate of Immunization, Islamabad

PREFACE

Standard operating procedures are crucial for the efficient and effective functioning of a vaccine warehouse. The aim of developing this document is to assist the FDI in optimizing vaccine inventory and cold chain management. The standard operating procedures will serve as a reference document for the FDI staff in ensuring the safety, quality, compliance, and efficiency of vaccine warehousing operations. The document provides a framework for consistency, mitigate risks, promote adherence to regulatory standards, and management of vaccines in the warehouse. The manual will play a crucial role in improving the vaccine logistics management system and properly organizing record keeping.

We would like to express our sincere gratitude to our colleagues and friends at USAID, both in Islamabad and Washington, who provided invaluable leadership support throughout this project. Special thanks to Mr. Bradley Cronk, Dr. Shabir Chandio, Mr. Khalid Mahmood, Mr. Sherif Mowafy, Mr. John Vivalo, Mr. Keith Hummel, and Mr. Ramy Guirguis for their contributions and dedication.

Together, we strive to improve vaccine logistics and contribute to a more efficient and effective healthcare service delivery system in Pakistan.

Dr. Muhammad Tariq

Zhofinth

Country Director

USAID Global Health Supply Chain Program – Procurement and Supply Management

INTRODUCTION

Standard operating procedures (SOPs) are process document that detail how a worker should perform a given task and ensures that all storekeepers, workers, and laborers, under the supervision of the Store Officer and the Assistant Store Officer perform tasks in the same way, which will consistently produce the expected outcomes.

SOPs, used in combination with planned training and regular performance feedback, lead to an effective and motivated workforce.

This manual, Warehouse Standard Operating Procedures, will help operators and workers at the FDI Warehouse to streamline the vaccine logistics, supply chain, and inventory management.

All the staff must adhere to these SOPs in maintaining ISO certified environment for maintaining an International Organization for Standardization (ISO) certified warehousing environment including storage, distribution and inventory management.

ISO CERTIFICATION REQUIREMENTS AND PROCESSES

The ISO 9001:2008 requires a documented quality management system. General requirements include an organization to establish, document, implement, and maintain a quality management system and continually improve its effectiveness.

Quality management system documentation requires:

- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures
- Documents needed by the organization to ensure the effective planning, operation, and control of its processes
- Records

ISO 9001:2008 specifically requires the organization to have documented procedures for the following reasons:

- Control of documents
- Control of records
- Internal audit
- Control of non-conforming products
- Corrective action
- Preventive action

An ISO certification will not only ensure that quality is maintained within the premises, but also will establish credibility of its operations locally and internationally.

1.0 RECEIPT PROCEDURE

1.1 COLD STORE

1.1.1 RESPONSIBILITY

The Storekeeper, under the supervision of Store Officer/Assistant Store Officer, is responsible for receiving all the vaccines at the FDI Warehouse.

1.1.2 PROCEDURE FOR VACCINES PURCHASED FROM INTERNATIONAL RESOURCES

1.1.2.1 Pre-alert shipment intimation

- For vaccines purchased through the international sources, the FDI Warehouse must receive shipment pre-alerts and shipping documents by email or fax at least 10 days prior to the arrival. Documents will include:
 - ✓ Shipping information from procuring agency/freight forwarding agent (Annex 1)
 - ✓ Copy of air way bill (AWB)- (Annex 2)
 - ✓ Copy of packing list (Annex 3)
 - ✓ Copy of invoice (Annex 4)
 - ✓ Copy of release certificate (Annex 5)
- Upon the arrival of advance intimations, delivery schedule for the Vaccine Arrival Date (VAD), storekeeper will check the documents, and will:
 - ✓ Check for availability of space and placement of incoming stock in the Freezer Room/Cold Room (FR/CR) of the Warehouse Management System/ vaccine logistics management information system (WMS/vLMIS)
 - ✓ Will record the flight arrival details in system as well as in shipping documents, record register and make arrangements for the collection of vaccine from the airport.
- Store officer will appoint a person who will deliver the shipment documents for the preappointed clearing agent at the port or airport for custom clearance.



 Will coordinate with the customs clearing agents and prepare the schedule for unloading, after consulting with them.

- Will confirm the readiness to receive vaccines by telephone or email if the airline requires doing so as a condition of delivery.
- Will arrange for the refrigerated trucks to be at the airport in time to collect the vaccine.

1.1.2.2 Collection of vaccine from the Airport

- Authorized clearing agent will clear the shipment through customs immediately after arrival of the flight and will deliver the shipment to FDI Warehouse preferably within six hours, but not later than 10 hours.
- Nominated FDI Warehouse person will transport the vaccine to the primary store by refrigerated vans and unload the vehicle immediately upon arrival.

1.1.2.3 Shipment inspection

- Before the inspection, the officer in-charge at the FDI Warehouse must ensure that all vaccines, including those received from international sources, are licensed for use in their country.
- The following documents that accompany the shipment must be checked:
 - ✓ Invoice
 - ✓ Packing list
 - ✓ Lot release certificate for the country of origin/Protocol Certificate (Annex 6)
 - ✓ Vaccine Arrival Report (VAR)-(Annex 7)
- After the vaccines arrive at the FDI Warehouse, unload the refrigerated van, inspect the shipment, and check for physical damage or missing items.
- The following steps must be completed while inspecting the new shipment:
 - ✓ Count the packages according to the packing list
 - ✓ Segregate each batch of vaccine and diluents/droppers
 - ✓ Open each carton and stop the electronic shipping indicators (Data Loggers/Q-Tag or similar)
 - ✓ Check the vaccine vial monitor (VVM) status (Annex 8), and type and expiry dates for each type and batch of vaccine
 - ✓ Perform vaccine Shake Test (Annex 9) to determine whether the vaccine is frozen or not
 - ✓ Segregate ice packs/coolants from the vaccine and properly store them.
 - ✓ Dispose of dry ice, if received with stock
- Record the status of VVM stage, type, and expiry date of vaccine in the VAR.

 Note: Do not record details of more than one vaccine type on a VAR. A separate VAR form must be completed for each vaccine—e.g., one for Oral Polio Vaccine (OPV), one for Bacillus Calmette-Guérin (BCG), etc.
- Check the status of the electronic shipping indicators. Record the details of any alarms on the Electronic Device Alarm Report form (Annex 10)
- If there are no electronic shipping indicators, check the status of the cold chain monitoring (CCM) cards and record any color changes on the CCM card. Make a photocopy or scan the card; record the color change details and ensure its usability under the World Health Organization (WHO) and manufacturer guidelines.
- For diluents that accompany reconstituted vaccines, such as BCG or measles vaccine check the batch number, expiry date; and confirm that they comply with the order requirements.
- For droppers, in the case of oral polio vaccine, check a sample of the products to confirm that they comply with the order requirements.
- Record all other required details for each vaccine in the shipment on the VAR form supplied for that vaccine.

- Hand over a copy of the VAR to the procurement agencies office within 72 hours of the flight's arrival
- For each received shipment, of vaccine, a separate checklist is filled out for reporting and record keeping, as shown below:

Received Shipment Checklist

Date	Purpose	Antigen	Batch No	Manufacture	Received From

1.1.2.4 Stock placement

1.1.2.4.1 Vaccine accepted

If no problems are identified, and the vaccine is accepted, unpack the shipping containers and place the vaccine in the cold chain (FR/CR, refrigerator, or freezer). Place diluents in the diluent dry store. After physically stacking vaccines in the cold chain, enter the received vaccine quantity in the Stock Receive Form of the vLMIS as shown below, and place them into the designated FR/CR in the vLMIS, as already mentioned above.

Stock Receive (Supplier)



The following points must be filled in the Stock Receive Form of the vLMIS:

- Reference number
- Received from
- Purpose
- Name of vaccine/product
- Manufacturer of the vaccine
- Vial presentation (doses per vial)
- Batch number(s)
- Expiry date
- Quantity of vials received
- VVM type
- VVM stage
- Name of cold chain equipment where the vaccine is kept

1.1.2.4.2 Vaccine rejected

- In case of unusable VVM stage and type or expired vaccine, and if problems or discrepancies are
 identified, immediately report the concerns to the supplier representative. If issues are identified, do
 not unpack the vaccine until the issue is resolved.
- Till reaching the resolution, stack the affected shipping container(s), with the temperature monitoring device(s), in holding area of designated FR/CR, as appropriate. Clearly mark each container "DO NOT USE." Place any associated diluents in a designated area of the diluent dry store.
- DO NOT record the arrival in the vLMIS.
- The storekeeper will retain VARs and all correspondence relating to the unsatisfactory shipments or procedures for a minimum period of 5 years.

1.2 VACCINE INVENTORY MANAGEMENT

1.2.1 RESPONSIBILITY

The storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for the vaccine inventory management.

1.2.2. PROCEDURE

- Ensure that all receipts and the dispatched transaction of the vaccine stocks are recorded in the WMS/vLMIS or in the stock register, daily.
- No transactions can be made outside the vLMIS and no supplies can leave the store without an Issue and Receipt Vouchers (IRVs) generated by the vLMIS.
- Ensure that full details of all transactions are completely entered immediately, as they occur.
- To identify the status of inventory for each vaccine, ensure that all vaccine stock has stock cards and bin cards updated and placed in front of each vaccine lot or batch.
- Physically compile and reconcile the dispatched and received vaccine stock in the FDI Warehouse with the quantities reflected in the WMS/vLMIS or stock register.
- Ensure that the vaccine commodities information on the WMS/vLMIS, or stock register, reconciles with the physical stock, location, rack, and pallet.
- Physically monitor and check all vaccines for the name, location, rack, pallet, lot, and batch; and ensure they are correctly identified in the WMS/vLMIS or stock register.
- Identify and correct any incorrect entries in the FR/CR location, rack, and pallet, and in all areas of the warehouse.
- Manually prepare and record the dispatched and received vaccine commodities on a daily basis and report it in the WMS/vLMIS or in the stock register.
- Stock records, such as IRVs must be up to date in the vLMIS. Data files must be backed up daily and the backup media must be kept in a safe place.
- To obtain prints of the vaccine stock sufficiency reports and reviews, have the relevant FDI Warehouse authority sign them and file them.
- Identify and take precautionary measures to safeguard vaccine stock from loss, theft, damage, and expiry.
- Ensure that all features of the WMS /vLMIS are working appropriately and are error free and that any problems that occur with the WMS/vLMIS are reported immediately.
- Ensure that all the WMS/vLMIS equipment is running smoothly, and that it is kept and maintained in good condition.
- Ensure that all vaccine commodities placed in the FDI Warehouse are scanned and arranged by location in each FR/CR.
- Ensure that the vaccine and supplies commodities are released based on the First to Expire, First-Out (FEFO); and that any short expiry is reported immediately to management.

1.3 DRY STORE

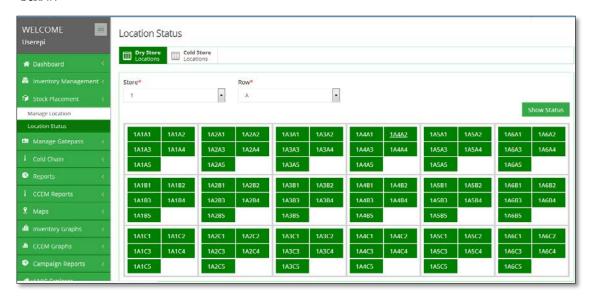
1.3.1 RESPONSIBILITY

The Storekeeper, under the supervision of the Store Officer/Assistant Store Officer, is responsible for receiving all ancillary supplies at the FDI Warehouse. Supplies in dry store contain syringes, safety boxes, vitamin capsules, refrigerators, freezers, cold boxes, and vaccine carriers etc.

1.3.2 PROCEDURE

1.3.2.1 Shipment Pre-alert

- The FDI Warehouse must receive pre-alert shipment intimation and documents by 10 days before the arrival of supplies.
- Get delivery schedule for Product Arrival Date (PAD); and prepare proper logistics and administrative arrangement in advance.
- Check available space and plan placement of incoming stocks and update in the vLMIS as shown below:



- The following must be checked in the shipment, pre-alert documents:
 - ✓ Shipping notification from freight forwarding agent to concerned FDI Warehouse staff.
 - ✓ Copy of packing list (Annex 12)
 - ✓ Copy of invoice (Annex 13)
- Check these documents and file them in the product arrival file.
- FDI Warehouse concerned authorities will deliver the shipment documents for the pre-appointed clearing agent at the port or airport for custom clearance.
- Closely coordinate with the customs clearing agent and prepare the schedule for unloading.

1.3.2.2 Collect Shipment from the Port of Entry

- Clear the shipment through customs within maximum allowable period preferably less than 24 hours of flight arrival.
- Transport the products to the store or warehouse and immediately unload the vehicle.

1.3.2.3 Shipment Inspection

- Inspect the shipment when it arrives at the FDI Warehouse and check for physical damage or missing items.
- Check following documents accompanying the shipment;
 - ✓ Invoice
 - ✓ Packing list
 - ✓ Certificate of conformity (Annex 14)
 - ✓ Copy of Product Arrival Report (PAR) (Annex 15)
- Syringes: Check the lot numbers, expiry dates, and/or manufacturing dates and confirm that they comply with the order requirements
- Safety boxes: Check a sample of the products to confirm that they comply with the order requirements.
- Vitamin A capsules: Check the batch numbers, and manufacturing and expiry dates, and confirm that they comply with the order requirements.
- Single-use electronic devices: This category includes freeze indicators and 30-day refrigerator temperature loggers. Check the lot numbers, expiry dates, and/or manufacturing dates; and confirm that they comply with the order requirements.
- Refrigerators and freezers: Check that the model numbers comply with the order requirements and that all loose components, such as vaccine baskets and spare parts, have been supplied.
- Cold boxes and vaccine carriers: Check that the model numbers comply with the order requirements and that the correct number and type(s) of water packs have also been supplied.
- Record all required details for each product in the Product Arrival Report (PAR).
- If no problems are identified and the products are accepted, transport them to the correct store or warehouse.
- If problems are identified, stack the unopened shipment on pallets or shelves in a designated area. Clearly mark the shipment "DO NOT USE."
- If problems have been reported, the Storekeeper will carry out follow-up activities, as agreed with supplier/procuring agent.

Received Shipment Checklist

Date	Purpose	Item	Batch No	Manufacturer	Received From

1.3.2.4 Stock placement

1.3.2.4.1 Shipment accepted

If no problems are identified and the product(s) are accepted, stock them in the correct store/location.

1.3.2.4.2 Shipment rejected

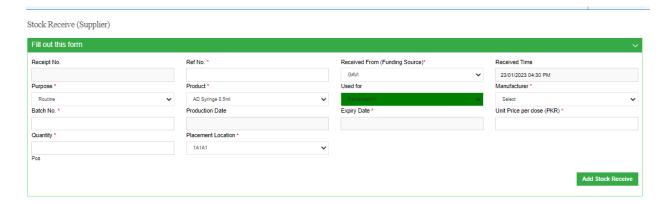
Any problems/ discrepancy/rejection due to damage/non- conformance with shipping documents should be immediately brought to the attention of the procuring agency through the FDI. Do not merge the disputed stock with the active inventory until a final decision is reached.

- Stack the unopened shipment on pallets or shelves in a designated area. Clearly mark the shipment "DO NOT USE."
- Retain PARs and all correspondence relating to unsatisfactory shipments or procedures for a minimum of 5 years.

1.3.2.5 Stock Received in vLMIS

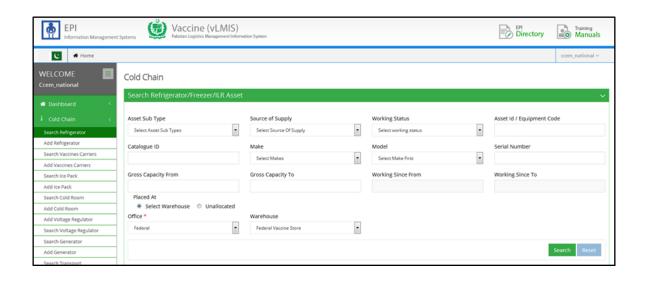
1.3.2.5.1 Syringes and safety boxes

- After receiving and unpacking the entire stock, physically place all the stock in their respective racks, pallets, and bins.
- Correctly enter the received stock into stock using the Stock Receive form of the vLMIS, as shown below and place them into the designated Dry Store Location in the vLMIS as already mentioned above.



1.3.2.5.2 Refrigerators, freezers, vaccine carriers, and cold boxes:

Record the arrival in the stock control system, including manufacturer's name, model, and serial number. Record the required product details in the national cold chain equipment inventory.



2.0 STORAGE

2.1 COLD STORE

2.1.1 RESPONSIBILITY

The Storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for the storage of vaccines and supplies at the cold and dry stores at the FDI Warehouse.

2.1.2 PROCEDURE

- Remove the primary packings of vaccine from cartons and place them in the FR/CRs.
- Store ice packs or coolants received in the FR/CRs.
- Clean soiled or dusty exteriors of cartons before placing those in the stores and/or FR/CRs.
- Place the different vaccines in the FR/CRs in an appropriate space between each inner box, block, or tray of vaccine, which will allow the cold air to circulate around the vaccine.
- Store vaccines that have similar packaging in different locations in the cold/refrigerator rooms to avoid confusion and medication errors.
- Place the heat sensitive vaccines in the freezer rooms and other vaccines in the cold rooms.
- Do not place the freeze sensitive vaccines in freezer rooms.
- Vaccines for reconstitution can be placed in both the FR/CRs.
- Place each vaccine carton on the allocated shelf in the FR/CR's lot wise.
- Vaccines stored on pallets or racks should be free from moisture, dirt, insect, or rodent contamination.
- Clean up broken or spoiled product in a timely manner.
- Place proper tags on the vaccines shelves and racks including information on vaccine name, manufacturer, purpose, expiry date, and vaccine arrival date.
- Clearly label with the specific vaccine name, the location of each specific vaccine inside the cold/refrigerator or the storage unit room.
- Inspect that the cold chain equipment is functioning correctly; if any problem is noticed, immediately inform the cold chain mechanical engineer.
- Using the vaccines repacking protocols, repair and repack damaged cartons of vaccines before they are placed in the cold/refrigerator rooms. Rotate vaccine stock once a week; place them in the FR/CRs based on the expiration date, once a week and every time a new vaccine shipment arrives.
- Set the temperature alarms in the cold/refrigerator rooms; update the temperature logs daily.
- On a daily basis, randomly check the quality of the vaccines, or do a vaccine Shake Test of the suspected batch or lot.
- Disinfect and spray the storage area every third month against insects, rodents, and harmful bacteria, which are threats to the dry supplies and the health of the staff.
- Place and update the vaccine tags located in the appropriate FR/CR any time the status of stocks changes.
- Perform a physical count periodically—monthly, quarterly, and annually—to detect discrepancies.
- Restrict access to storage areas for vaccines to authorized personnel only.

- Record the FR/CR temperature on the logbook or chart twice a day to verify that the storage temperature is within the acceptable temperature ranges of +2°C to +8°C in cold rooms and vaccine refrigerators and -25°C to -15°C in the freezer room and freezers.
- This temperature chart also helps detect temperature alarm conditions that may cause vaccine damage and allows appropriate action to be taken; to assess the performance, over time, for vaccine handling at each link of the cold chain; and to monitor the performance of cold chain equipment.
- A temperature chart for FR/CRs is shown below:

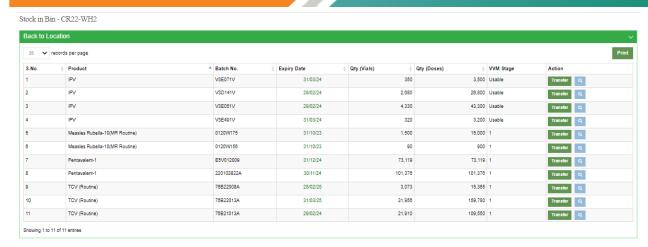
Temperature Chart

Date	AM	°C	Initial	PM	°C	Initial
				_		

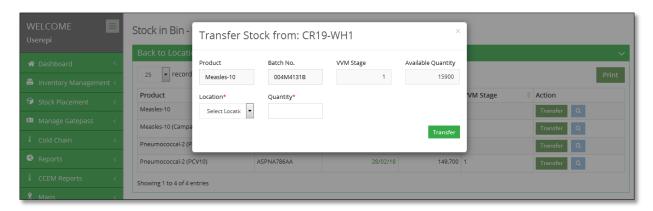
After receiving stock, both physically and in the vLMIS, locate/place the received stock into the designated CRs/FRs of the vLMIS, as shown below:



By clicking on the required FR/CR, stock can be placed, as shown below:



By clicking on transfer button, stock can be transferred from one bin to another, as shown below:



2.1.3 STORAGE OF SHIPMENT CHECKLIST

A checklist for storing a shipment of vaccine received is shown below:

Storage											
		Is Stock received according to prescribed alert?					Total Primary Boxes Per Secondary Box			Carton	Cold Room Number/ Freezer Number in which vaccines are placed

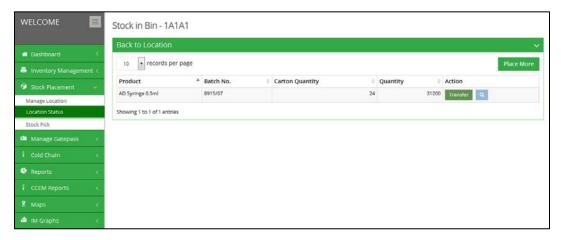
- Place and store the diluents and droppers accompanying the vaccine shipments in the designated bins of the racks in the dry warehouse at room temperature.
- Correctly place and enter the quantities of diluents and droppers on their respective bins in the WMS/vLMIS, as placed in the warehouse.

2.2 DRY STORE

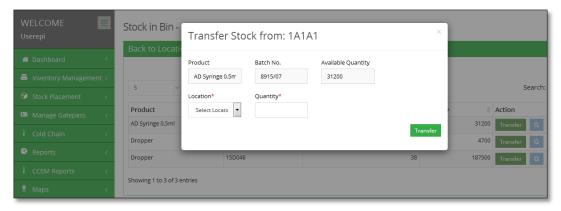
After receiving stock, both physically and in the vLMIS, locate/place the received stock into the designated bins, pallets, and racks of the vLMIS, as shown below:



By clicking on the required bin, stock can be placed, as shown below:



By clicking on transfer button, stock can be transferred from one bin to another, as shown below:



- All products are safely stored within the temperature and humidity levels specified for the product type.
- Access to storage areas—including products, packaging materials, and exterior storage areas—must be restricted to authorized personnel only.
- Store diluents, syringes, and other products with a limited shelf life in a separate location so they can easily be located and distributed in FEFO order.
- Store products without an expiry date, such as safety boxes, in a separate location so they can easily be located and distributed in FEFO order.
- Keep expired or damaged products marked for disposal separate from usable stock.
- Using the supplies repacking protocols, repair and repack damaged cartons of dry supplies before they are
 placed on the racks and pallets in the dry store.
- Rotate stock once a week, based on the expiration date and every time a new shipment arrives.
- Use proper stackers to place pallets in the allocated racks or area; ensure that cartons or pallets are not leaning over the edge of the racks or shelves.
- Maintain pallets, racks, and equipment in good condition to prevent any physical damage to materials or products (e.g., free from nails, wood splinters etc.).
- Keep the dry storage area clear and clean; keep the aisles empty to enable the stacker to operate and to allow people to walk through.
- Randomly check the quality of the dry store supplies daily.
- Disinfect and spray the storage area every third month against insects, rodents, and harmful bacteria, which are threats to the dry supplies and the health of the staff.
- Use stackers to place pallets on the racks.
- Place and update the diluent bin cards in the dry warehouse any time the status of stocks changes.
- Do a physical count periodically—monthly, quarterly, and annually—to detect discrepancies.
- Place received refrigerators or ice-lined refrigerators (ILRs), vaccine carriers, and cold boxes in the dry warehouse of the FDI Warehouse.
- Ensure that the dry supplies carton is secure and properly packed on all sides.

3.0 ISSUE PROCEDURE

3.1 COLD STORE

3.1.1 RESPONSIBILITY

The Storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for issuing vaccines and supplies to provinces and districts at the FDI Warehouse.

3.1.2 PROCEDURE

- Acquire the complete signed requisition/demand of vaccines from all provinces, including the public- and private-stakeholders.
- Relevant officials of FDI will review and analyze the vaccine requirements for each stakeholder; to fulfill the requirement against the availability of vaccine stock in the FDI Warehouse.
- Approval sheet, or the release order request, for the requested vaccines will be shared with store officials.
- The approval sheet should contain the essential information, including the quantity requested by the province and district and the current stock status at the FDI Warehouse.
- The approval sheet for the resale of vaccines will include a recommendation to decrease the number of vaccines based on the actual demand by clients, after a stock sufficiency analyses.
- Vaccines will be issued to all province stakeholders that maintain the minimum/maximum level of vaccine stock at the FDI Warehouse.
- Prepare the vaccine dispatch order sheet/release order that has all the necessary information related to the requested vaccines.
- Generate the electronic vaccine picking list/priority vaccine distribution list from the vLMIS, as shown in the figure below:

Priority Vaccines Distribution

					Summary	Detail
Product	Batch Number	Expiry Date	VVM	Cold room	Quantity (Vials)	Quantity (Doses)
Priority 2	•					
bOPV (Campaign)	U3P511V	Nov, 2023	Usable	FR18-WH1	15,090	301,800
				Total:	15,090	301,800
Priority 3						
bOPV (Campaign)	202202008	Feb, 2024	Usable	FR14-WH1	3,611	72,220
bOPV (Campaign)	202202011	Feb, 2024	Usable	FR14-WH1	1,620	32,400
bOPV (Campaign)	AOP4A710AA	Mar, 2024	Usable	FR36-WH1	19,800	396,000
bOPV (Campaign)	V3F721V	Apr, 2024	Usable	FR20-WH1	11,946	238,920
bOPV (Campaign)	2042322	May, 2024	Usable	FR44-WH2	800	16,000
bOPV (Campaign)	AOP4A720AA	May, 2024	Usable	FR48-WH2	158,942	3,138,840
bOPV (Campaign)	AOP4A721AA	Jun, 2024	Usable	FR34-WH1	22,200	444,000
				Total:	216,919	4,338,380
Priority 2						
Measles Rubella-10(MR Routine)	0120W099	Jul, 2023	1	CR41-WH1	161	1,610
Measles Rubella-10(MR Routine)	0120W138	Sep, 2023	1	FR32-WH1	3,350	33,500
Measles Rubella-10(MR Routine)	0120W140	Sep, 2023	1	CR45-WH2	300	3,000
Measles Rubella-10(MR Routine)	0120W179	Oct, 2023	1	FR07-WH1	1,200	12,000
Measles Rubella-10(MR Routine)	0120W171	Oct, 2023	1	CR08-WH1	6,600	66,000
Measles Rubella-10(MR Routine)	0120W175	Oct, 2023	1	CR22-WH2	1,500	15,000

• For vaccines going by air, calculate the number of cartons, vials, diluents, and droppers, as per requisition.

3.2 PACKING VACCINES

3.2.1 RESPONSIBILITY

The Storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for all packing of vaccines and supplies at the FDI Warehouse.

3.2.2 PROCEDURE

- All the store staff must ensure that they wash their hands thoroughly before handling vaccine cartons and vaccine vials.
- Sort, pick, and pack the different vaccine, as per the packing protocols for each vaccine from the allocated cold/refrigerated rooms.
- Only open the FR/CRs door when necessary; for example, when preparing for vaccine repacking.
- Organize all types of vaccines per the requisition/demand form; segregate them in the different FR/CRs
- For dispatch of vaccines for far destinations and outreach sessions, follow packing protocols for specific vaccines in order to minimize the risk of damaging the vaccines.
- Before packing, prepare conditioned ice packs (Annex 11) and water coolants, as per the following instructions.

3.2.2.1 Prepare Ice Packs/Cool Water Packs

- Establish requirements: Calculate the number of ice packs/cool water packs/warm water packs needed for each delivery. Calculate how long it will take to prepare them.
- Prepare ice packs: Place the required number of water packs in a freezer room or freezer that is kept at a temperature between -5°C and -25°C. Leave them until they are fully frozen. If an ice pack fast freezer is used to freeze the ice packs, move the fully frozen ice packs to a conventional freezer or to cold boxes for storage purposes.
- Prepare cool water packs: Place the required number of water packs in a cold room or refrigerator that is kept at a temperature between +2°C and +8°C. Leave them to stabilize for a minimum of 12 hours
 - <u>Cold rooms</u>: DO NOT allow the temperature of the cold room to rise above +8°C during the cooling process. DO NOT allow water packs to touch the vaccines.
 - <u>Refrigerators</u>: Use a dedicated refrigerator. DO NOT cool water packs in a refrigerator that contains vaccine.

3.2.3 PACKING PROCEDURES

3.2.3.1 Packing vaccines that are not damaged by freezing

The following vaccines are NOT damaged by freezing. They can safely be packed and transported using fully frozen ice packs at all times of the year.

- ✓ OPV—monovalent, bivalent, and trivalent
- **✓** BCG
- ✓ measles

The following points must be ensured before packing these vaccines:

- Use the correct size and number of ice pack for the chosen cold box. Line the cold box exactly as described on the instructions given inside of the cold box lid.
- Pack the vaccine cartons in the cold box with the vial caps facing up.
- Use newspaper or other loose packing to ensure that the load cannot shift during transport.
- Place a freeze indicator device in the box on top of vaccines.
- Place a packing list in the box on top of the vaccine.

- Label the box with the final destination of placement.
- Close the lid and engage the catch.
- Keep the cold box in the packing room, or in a covered holding area, until all other boxes in the consignment have been packed.
- Keep the cold box away from direct sunlight during transport.

3.2.3.2 Packing freeze-sensitive vaccines using conditioned ice packs

The following vaccines ARE damaged by freezing and must always be packed as described below:

- ✓ hepatitis B (Hep B)
- ✓ pentavalent (DTP-Hep B-Hib)
- ✓ pneumococcal vaccine (PCV-10)
- ✓ tetanus toxoid vaccine (TT)

The following points must be ensured before packing these vaccines:

- Condition the required number of frozen ice packs as described (Annex 14) for conditioning frozen ice packs.
- Use the correct size and number of fully conditioned ice packs for the chosen cold box. Line the cold box exactly as described in the instructions on the inside of the cold box lid.
- Pack the vaccine cartons in the cold box with the vial caps facing up.
- Use newspaper or other loose packing to ensure that the load cannot shift during transport.
- Place a packing list and freeze indicator device in the box on top of the contents.
- Label the box with the final destination of the placement.
- Close the lid and engage the catch.
- Keep the cold box in the packing room, or in a covered holding area, until all other boxes in the consignment have been packed.
- Keep the cold box away from direct sunlight during transport.

3.2.3.3 Packing freeze-sensitive vaccines using cool water packs

The following vaccines ARE sensitive to freezing and must always be packed as described below:

- ✓ hepatitis B (Hep B)
- ✓ pentavalent (DTP-Hep B-Hib)
- ✓ pneumococcal vaccine (PCV-10)
- ✓ tetanus toxoid vaccine (TT)

The following points must be ensured before packing these vaccines:

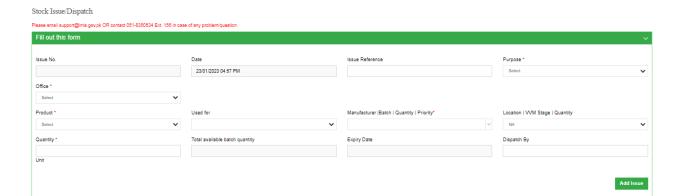
- Use the correct size and number of cool water packs (+2°C to +8°C) for the chosen cold box. Line the cold box exactly as described in the instructions on the inside of the cold box lid.
- Pack the vaccine cartons in the cold box with the vial caps facing up.
- Use newspaper or other loose packing to ensure that the load cannot shift during transport.
- Place a packing list and freeze indicator device in the box on top of the vaccines.
- Label the box with the final destination of the placement.
- Close the lid and engage the catch.
- Keep the cold box in the packing room, or in a covered holding area, until all other boxes in the consignment have been packed.
- Keep the cold box away from direct sunlight during transport.

3.2.3.4 Packing diluents

- Pack inner diluent cartons in sturdy cardboard boxes or plastic crates.
- Use newspaper or other loose packing to ensure that the load cannot shift during transport.
- Place a packing list in the box on top of the contents.
- Label the carton with the final destination of the placement.
- Keep diluent cartons away from direct sunlight during transport.
- Keep the cold box away from direct sunlight during transport. Repack all the damaged/broken cartons of dry supplies before loading onto the truck.
- Ensure that the cartons are sealed with plastic tape for protection and to ensure the cartons do not break at the edges.

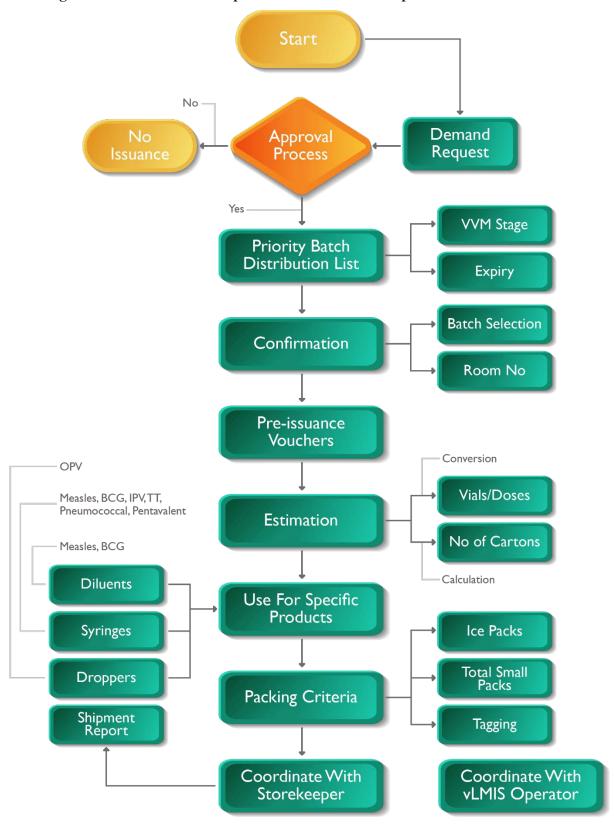
Note: If diluents are frozen, the glass ampoule is likely to break, so they must never be exposed to temperatures below 0°C.

- After packing all the vaccines into cartons, according to set protocols, post tags on each repacked carton that includes the following information, signed by the Storekeeper and Store Officer:
 - ✓ Name of vaccine
 - ✓ Manufacturer
 - ✓ Consignee location to be dispatched
 - ✓ Expiry date of vaccine
 - ✓ Quantity in vials
 - ✓ Number of ice packs
- Provide a packing list/shipment report that includes the following information for all repacked vaccine cartons, duly signed by the Storekeeper and Store Officer
- Ensure that the provided repacking list is used to repack the correct item, and the correct quantity, for the correct stakeholder, and for the correct district.
- Scan the vaccines that have barcodes; update the WMS/vLMIS or stock register.
- For vaccines transported by refrigerated trucks, arrange the truck for the sorted dispatch; load and place the insulated containers of vaccines onto the refrigerated truck.
- Physically count the loaded vaccines in the presence of the truck driver or relevant person who removed the vaccines from the FDI Warehouse.
- The WMS/vLMIS operator generates the electronic issue and dispatch voucher for dispatching the vaccine consignment, which includes the following information, as shown in the figure below:
 - ✓ Reference number of demand letter/requisition
 - ✓ Issue reference
 - ✓ Date/time of issuance
 - ✓ Purpose
 - ✓ Office
 - ✓ Product
 - ✓ Batch number
 - ✓ VVM stage
 - ✓ Quantity in vials
 - ✓ Stock issue voucher in the vLMIS



- Prepare and print three copies of the Stock Issue/Dispatch Vouchers from the WMS/vLMIS and get the approval of the relevant authority of the FDI Warehouse.
- The vLMIS operator will issue a gate pass by vLMIS, which has the information for the dispatched quantity to the consignee.
- Give one copy of the issue voucher, signed by the Storekeeper, Store Officer, and receiver, including the gate pass, to the transporter; one copy for the receiver/consignee; and a third copy will be kept at FDI Warehouse as a confirmation that vaccines/supplies were delivered to and received by the consignee.
- Follow up with the freight forwarders/transporter for the timely deliveries of vaccines to the consignee.

The figure below summarizes the process of issuance and dispatch:

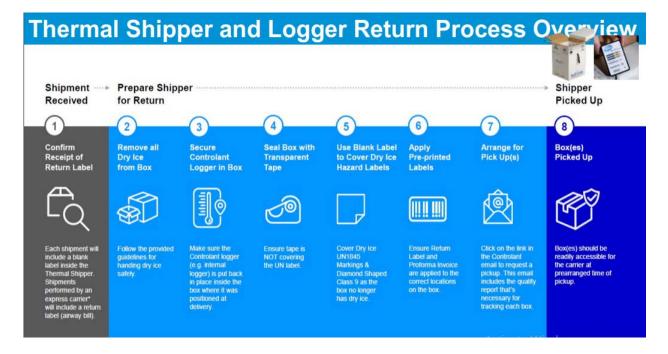


3.3 Reverse Logistics of Pfizer Vaccine

For COVID Pfizer-BioNTech vaccines (Adult and Pediatric), FDI apply Reverse Logistics to return back thermal boxes with Data Loggers to Pfizer for their reuse/recycle purpose as per Pfizer's global contract with donors and governments/countries for vaccine purchase.

Returning thermal shipping containers and real-time temperature monitors to the suppliers will help Pfizer fulfil its commitments to use reusable resources. The following instructions should be taken in accordance with the standard operation procedure to prepare the thermal shipping container for return:

- Upon arrival of Pfizer-BioNTech vaccine boxes at the FDI warehouse, all the Data Loggers to be stopped to secure the data and upload the current data on the Pfizer web portal.
- Properly discard the dry ice. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet.
- Remove the remaining dry ice by leaving it at room temperature in a well-ventilated area. It will change from a solid to a gas. "DO NOT" leave dry ice in an unsecured area.
- Make sure everything to be returned is inside the box, then tape it shut. The return label can be found inside the shipper or already adhered to the inner flap of the thermal shipper.
- Contact the carrier identified on the return label to arrange the return. Followed the Returning Thermal Shipping Container instructions included in the shipper. When coordinating the return of the Soft box thermal shipping container, applied the preprinted return shipping label over the existing shipping label.
- Below diagram illustrate the process of return of thermal shipper soft boxes:



Elements Required for Return

- Thermal Shipping container and inner components
- Temperature Monitoring Device
- Dry Ice Pod

Ensure the Dry Ice UN1845 marking and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice.

For Soft box, blank sticker labels to place over the UN1845 markings found on the back page of the Shipping and Handling Guidelines.





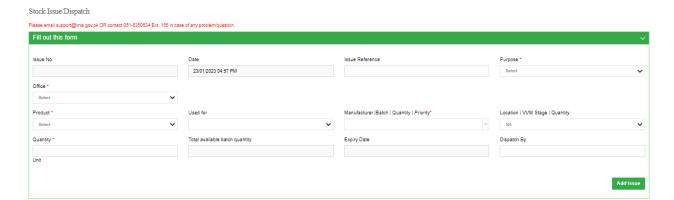
3.4 DRY STORE

3.4.1 RESPONSIBILITY

The Storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for issuing vaccines and supplies to the provinces and districts at the FDI Warehouse.

3.4.2 PROCEDURE

- Acquire the complete signed requisition/demand of compulsory dry supplies from all provinces, including the public and private stakeholders.
- Review and analyze the vaccine supplies requirements for each stakeholder; to fulfill the requirement, check the availability of the dry store stock in the FDI Warehouse.
- Prepare the approval sheet, or the release order request, for the requested supplies for approval from the relevant FDI Warehouse authority.
- The approval sheet should contain the essential information, including the quantity requested by the province and district and the current stock status at the FDI Warehouse.
- The approval sheet for the resale of supplies will include a recommendation to decrease the number of ancillary items of vaccines by the actual demand by clients, upon stock sufficiency analyses.
- Supplies will be issued to all province stakeholders that maintain the minimum/maximum level of vaccine stock at the FDI Warehouse.
- Prepare supplies dispatch order sheet/release order that has all the necessary information related to the requested supplies.
- Follow the criteria of FEFO for dispatch of batches.
- Sort, pick, and pack the different supplies as per the packing protocols of each dry store item, from the allocated racks, pallet location.
- Arrange supplies for loading.
- Arrange the truck for the sorted dispatch; load the consignment of supplies.
- Physically count the loaded supplies in the presence of the truck driver or relevant person who removed supplies from the FDI Warehouse.
- The WMS/vLMIS operator generates the electronic issue and dispatch voucher for dispatching the consignment, which includes the following information, as shown in figure below:
 - ✓ Reference number of demand letter/requisition
 - ✓ Issue reference
 - ✓ Date/time of issuance
 - ✓ Purpose
 - ✓ Office
 - ✓ Product
 - ✓ Batch number
 - ✓ Quantity in vials.



- Prepare and print three copies of the Issue/Dispatch vouchers from the WMS/vLMIS and get the approval
 of the relevant authority of the FDI Warehouse.
- The vLMIS operator will issue a gate pass by vLMIS, which has the information of the dispatched quantity to the consignee.
- Give one copy of the Issue/Dispatch voucher signed by the Storekeeper, Store Officer, and receiver, and
 including the Gate Pass to the transporter; one copy for the receiver/consignee; and a third copy will be
 kept at the FDI Warehouse as a confirmation that supplies were delivered to and received by the consignee.
- Follow up with the freight forwarders/transporter for the timely delivery of supplies to the consignee.

4.0 DISPOSAL

4.1 UNUSABLE VACCINE

4.1.1 RESPONSIBILITY

The Storekeeper under the supervision of the Store Officer/Assistant Store Officer is responsible for the maintenance and disposal of unusable vaccines and supplies.

4.1.2 PROCEDURE

- If, for any reason, vaccines are identified as unusable (expired, physically damaged from heat exposure and freezing etc.), the relevant FDI Warehouse or store authority should immediately stop distributing the unusable vaccine stock.
- Immediately separate the identified vaccine lot, batch, or any quantity identified in the FDI Warehouse as unusable stock.
- Store the container having unusable vaccines in a cold room or vaccine refrigerator until permission is given to take it out of the cold chain.
- Clearly mark the assigned storage area as "EXPIRED VACCINES FOR DISPOSAL-DO NOT USE," in the case of expired vaccines.
- Clearly mark as "DAMAGED VACCINES FOR DISPOSAL-DO NOT USE" in case of physically damaged vaccines, due to heat exposure (VVM color change) and freezing, so that items placed here cannot be confused with usable stock.
- If diluents also need to be removed from stock, place them in a container clearly marked "EXPIRED DILUENTS FOR DISPOSAL—DO NOT USE."
- Record and update the vLMIS regarding the expired vaccines or diluents. Prepare a loss and adjustment report.
- Immediately notify the relevant FDI Warehouse or store office authorities through the proper procedures and policies of the FDI Warehouse.
- By providing a detailed description of the unusable vaccine, the relevant FDI Warehouse higher authority can initiate further actions and can form a committee to identify why the vaccine stock was found unusable and arrange for its safe disposal.
- The committee will advise the FDI Warehouse relevant authority how to safely dispose of the unusable vaccines and diluents.
- The committee may finally decide to dispose of or use the identified vaccine stock, based on laboratory tests and other findings from the vaccine stock inspection.
- Hazardous/infectious vaccine waste must be disinfected and buried, incinerated, or disposed of by
 following specific and established procedures for disposing of vaccines (Please refer the FDI Logistics
 Manual).
- To ensure that expiries or damages do not occur again, the committee will provide a detailed report on the expiries or damaged vaccines stock, and the action and corrections that took place.

4.2 DAMAGED ANCILLARY ITEMS

- If, for any reason, ancillary items are identified as unusable (expired, damaged, etc.), the relevant FDI Warehouse or store authority should immediately stop distribution of the unusable stock.
- Immediately separate the identified lot, batch, or any quantity identified in the FDI Warehouse as unusable stock.
- Assign a separate well-ventilated room for these products. Clearly mark the assigned storage "PRODUCTS FOR DISPOSAL—DO NOT USE" so that items placed here cannot be confused with usable stock.
- Immediately notify the relevant FDI Warehouse or store authority through the proper procedures and policies of the FDI Warehouse.
- By providing a detailed description of the unusable ancillary items, the relevant FDI Warehouse higher authority can initiate further actions and can form a committee to identify why the stock was damaged or expired and arrange for its safe disposal.
- The committee will advise the FDI Warehouse relevant authority how to safely dispose of the unusable supplies.
- The committee may finally decide to dispose of the unusable stock either through incineration or by landfill. Other methods may include inertization, chemical treatment, or by using sharps pits.
- To ensure that expiries or damages do not occur again, the committee will provide a detailed report on the expiries or damaged vaccines stock, and the action and corrections that took place.

5.0 ANNEXURES

COLD STORE

ANNEX-1 SHIPPING INFORMATION (SAMPLE)

****PRE-ADVICE****

UNICEF PAKISTAN

From: CJ KOREA EXPRESS

Pages: Total 09 pages including Pre-Advice Cover Sheet

Date:

To:

PART SIX

PO NUMBER: CUST. REF.: PCS: KGS CBM: COMMODITY: NUMBER OF VIALS: VALUE: AWB NO.:

45143062 PSS-GAVI-PAK-15 PENTA VA 93 4.557KG 29.40CBM DTP-Hep-Hib fully liquid vaccine 390,000 USD916,500.00 157-9437 8760

FLIGHT: ICN / DOH QR859/17.FEB (00:05~04:15)

DOH/ISB QR632/17.FEB (19:40~01:00)+1

ETA ISB: 01:00 HRS/18 FEB 2016

막침쾌/보둑당)수송운웨디트/20160202133716

Crucell

Summary Protocol for the Production and Testing of DTwP-HepB-Hib Fully Liquid Combination Vaccine

FINAL PRODUCT

IDENTIFICATION OF FINAL LOT

	20 III
Name and address of manufacturer	Berna Biotech Korea Corp. (Songdo-dong) 23, Harmony-ro 303beon-gil, Yeonsu-gu, Incheon, 406-840 Korea
International name and proprietary name of vaccine	Diphtheria-Tetanus-Whole Cell Pertussis-Hepatitis B (cDNA)-Haimophilis influenzae type b-conjugated to Diphtheria CRM197 Combination Vaccine (DTwP-HepB-Hib Fully Liquid Combination Vaccine), Quinvaxem ⁶ inj.
Lot number of final product	1453338
Date of manufacture of final lot	2014.08.25.
Type of container	Vial
Quantity of manufacture (unit : vials)	726,432
Number of doses in each container	1 dose/vial
Volume of single dose	0.5 mL/dose
Expiry date	2017.08.24.

Quinvaxem [®] inj.	Berna Biotech Korea Corp.	Lot No. 1453338
Summary Protocol (Ver. 2.1)	Berna Bioteca Korea Corp.	Page 1 of 16

ANNEX 2- AIR WAY BILL (SAMPLE)

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ANNEX 3- PACKING LIST (SAMPLE)

PACKING LIST 24.08.2015 Page 1/1

SANOFI PASTEUR 🗳



DELIVERY NR : 0080591591

ORDER NR : 0000164340

CONSIGNER sanofi pasteur 2 Avenue Pont Pasteur Boite Postale : BP 7046 69367 LYON Cedex 07 France

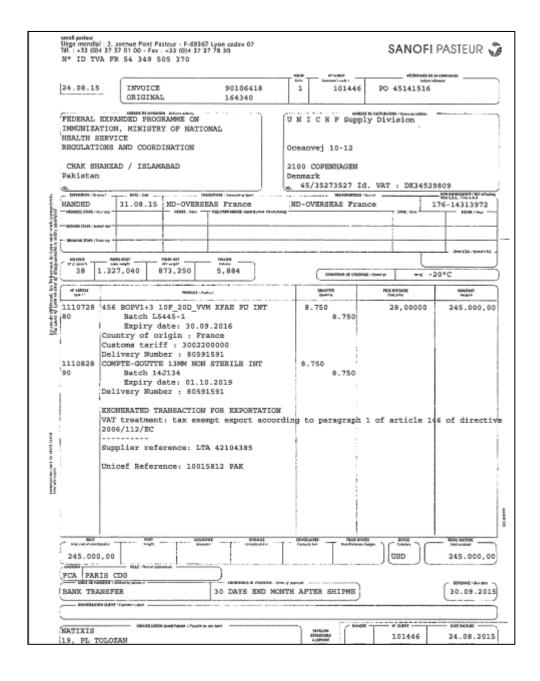
CONSIGNEE FEDERAL EXPANDED PROGRAMME ON IMMUNIZATION, MINISTRY OF NATIONAL HEALTH SERVICE REGULATIONS AND COORDINATION CHAK SHAHZAD / ISLAMABAD

Pakistan

NR PACKAG E	GROSS WGHT BY PACKAGE	NET WEIGHT BY PACKAGE			LxHxW		
	MATERIAL DE	SCRIPTION			BATCH NR	SHELF LIFE	QUANTITY BY PACKAGE
1 to 19	53,640	37,312	0,215	71	LX60,8X50		
	456 BOPV1+3	10F_20D_VV	M XFAE PU		L5445-1	30.09.2016	440
20	49,740	33,072	0,215	73	X60,8X50		
	456 BOPV1+3	10F_20D_VV	M XFAE PU		L5445-1	30.09.2016	390
21 to 37	9,004	7,500	0,089	į	51X39X45		
	COMPTE-GOUT	TE 13MM NON	STERILE		14J134	01.10.2019	500
38	5,070	3,750	0,071	462	(43,5X35,5		
	COMPTE-GOUT	TE 13MM NON	STERILE		14J134	01.10.2019	250

NUMBER OF PACKAGES: 38 1227,040 873,250 5,884 TOTAL GROSS WEIGHT (KG) TOTAL NET WEIGHT (KG) TOTAL VOLUME (M3) :

ANNEX 4- INVOICE (SAMPLE)



ANNEX 5- RELEASE CERTIFICATE (SAMPLE)



Country :Pakistan

:100426, UNICEF Customer Order :7100016501/000020

CERTIFICATE OF RELEASE

GlaxoSmithKline Biologicals Rixensart - Belgium Manufacturer

Product Synflorix

Product description

Streptococcus Pneumoniae Polysaccharide Serotype (1,5,6B,7F,9V,14,23F) -PD Conjugate (1µg/d), Serotype 4-PD Conjugate (3µg/d), Serotype 18C-TT-AH Conjugate (3µg/d), Serotype 19F-DT Conjugate (3µg/d) Vaccine

Batch number ASPNA754BA

161.100 X 2 dose(s) Quantity

Expiry November/2017 Date of manufacture December/2014

I hereby confirm that this batch has been manufactured and controlled in compliance with the cGMP regulations and in accordance with the local regulatory requirements of the receiving market . This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC

> Qualified Person QA Director GSK Biologicals Rue de l'Institut 89 1330 Rixensart

Belgium

Sarah LOUAGIE Industrial Pharmacist

1 5 JUIL. 2015

32

ANNEX 6- PROTOCOL CERTIFICATE (SAMPLE)

NL41008



Document Name	Document Number	BRP Version Number
BRP - L5444 - STD (09-Apr-2015) - 1.0	BRP_327408	1.0
RELEASE PROTOCOL - B	IVALENT ORAL POLIOMYELITIS VACCIN	NE - Lot L5444

	Approver Name	Date (Universal Time)	Reason for Signature
Approval		09 Apr 2015 17:01:13	I am approving this document
	Effective Date:	09 Apr 2015	

Electronically approved by Qualified Person : The above electronic signature is legally binding and equivalent to individual's hand written signature as per the GMP and 21 CFR Part 11.

ANNEX 7- VACCINE ARRIVAL REPORT (SAMPLE)

This VAR is designed for any comments about the shipment, for example:

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								Coolant		Dry ice	k	cepacks		No co	oolant			
PART I - ADVA	NCE NOTIC	E						Tempera present	ture monitors	VVM 🗆	Cold	-chain card		Electron	ic devi	œ 🔲		Type:
MAIN DOCUMENTS	Date rec	seived by	Copy airway (AWB)		of packing Co	py of invoice	Copy of release certificate			TAILS OF STAT								
Pre-advice								(in addit	ion fill in ALA	RM REPORTING		there are	•		_): monitor	
Shipping notification			Yes 🔲 No	Yes [No Yes	No 📗	fes 🗌 No 🗌	Number	LO	TNO				<=-0.5°C			D	Date/time of i
List other documents (if requested)	Т						<u> </u>							Ш		\perp	
PART II — FLIGH	T ADDIVA	DETAILS	,					\vdash			\rightarrow	\rightarrow			Н	-	+	
PART II — FLIGH			,	F71		Ash of the	ne of arrival	\vdash			$\overline{}$				Н	\dashv	+	
AWB Number	Airpor destina		Flight No	Date Date	er notification Time	Date	Time				\neg				Н	\dashv	+	
											\neg				П		\top	
NAME OF CLEARING	AGENT:			ON BEHALF O)F:													
PART III — DETA	ILS OF VA	CCINE SH	IIPMENT														\perp	
Purchase			Vaccine des	scription				<u> </u>			\rightarrow				Н		+	-
Order No.	Consignee	+	(Type and do	oses/vial)	Manuf	acturer	Country	(Continue	on separate sheet	Frecessary)					Ш			
								PART	VI — GENI	ERAL CONDI	TIONS	OF SHIP	MENT					
	Vaccine					nt/droppers		Martin		of boxes on am	-0							
Lot Number	Number of boxes	Number of vials	Expiry date	Lot Nu	mber Numb		of Expiry date					_						
										attached to ship; ing description of								
								electroni	c devices:	sheet if necessar								
								(curano	on separate	THE STREET	11-							
			-															
			+															
(Continue on separate shee	it if necessary)																	
			Yes	No Cor	mmenta			PART	VII — NAM	E AND SIGN	ATURE							
Was quantity received	as per shippir	g notification									_	_				_		
If not, were details of s				+-				Authoriz	ed Inspection	Supervisor	DATE		Control str	ore or EPI Ma	103000			DATE
vaccine arrivat?	mon-ampment	ргомова рно	× to					Authoriz	eu mapecaon	Supervisor	DATE		Central Sit	Ne or Crima	anager			DATE
THE STATE OF THE S								For Proc	urement Agen	cy office use only								

- condition of the shipping cartons, inner boxes, vials, and droppers
- labeling on the shipping cartons—this should include a warning regarding the temperature-sensitive nature of vaccines and the shipment details (purchase order number, consignee information, and shipping carton number)
- labeling on the inner boxes and vials
- observations on any stages of the vaccine vial monitors (VVM)
- general condition of the shipment
- comments related to any previous sections of the VAR, such as documentation, delays, short shipment, or shipping indicators

ANNEX 8 – USING THE VACCINE VIAL MONITOR

A1.1: What is a VVM?

A VVM is a heat-sensitive label that is placed on a vaccine vial to register cumulative heat exposure, over time. The VVM is a circle with a small square inside it. The square contains a heat-sensitive dye.

A1.2: How does it work?

The combined effects of time and temperature cause the inner square of the VVM to darken—gradually and irreversibly:

- The lower the temperature, the slower the inner square changes color
- The higher the temperature, the faster the inner square changes color

A1.3: What are its limitations?

The VVM does not directly measure vaccine potency, but it does give information about the main factor that affects potency: heat exposure over a period of time.

Many liquid vaccines are also damaged by exposure to freezing. The VVM does **not** register information about freezing.

A1.4: What are the VVM stages?

There are only two WM stages:

- The **usable** stage is when the square is lighter than the circle
- The unusable stage is when the square matches the color of the circle, or is darker
- The **end point** is when the color of the square exactly matches the color of the circle

A1.5: How to read a VVM

Unusable stage

The square is lighter than the circle. If the square matches the color of the circle or is darker if the expiry date is not passed, the circle.

A1.6: Why are VVMs important?

The VVM shows whether the vaccine vial has been exposed to excessive heat, over time, and it indicates whether the vaccine is likely to have been damaged by this exposure. After the indicator reaches the **end point,** the vaccine should not be used.

A1.7: What types of VVM are available and how are they used?

Some vaccines are more sensitive to heat than others. For this reason, currently, four different types of VVMs are designed to match vaccines with differing heat stability. For example, VVM 2 is used with OPV because this is the most heat-sensitive vaccine; this VVM reaches its discard point after only 2 days at 37°C. In contrast,

hepatitis B vaccine is very heat-stable and the VVM 30 is used; it takes 30 days to reach its discard point at 37°C.

The table below describes the four VVM reaction rates by category of heat stability.

VVM Reaction Rates by Category of Heat Stability

Category		Time to End Point		Time to End Point
		at +37°C	at +25°C	at +5°C
VVM	30	30 days	193 days	>4 years
High stability			·	·
VVM	14	14 days	90 days	>3 years
Medium stability				·
VVM	7	7 days	45 days	>2 years
Moderate stability				
VVM	2	2 days	Not applicable	225 days
Least stable				

Note that vaccines made by different manufacturers can have different heat stability characteristics; the World Health Organization (WHO) will assign the different VVM categories. For example, one manufacturer's BCG might use VVM 30, while another type of BCG may need a VVM 14.

A1.8: Where is the VVM located?

VVMs are fixed to the vial or ampoule label of liquid vaccines. Under the Multi-dose Vial Policy (MDVP), they can be used in subsequent sessions. When the vaccine cannot be used in subsequent sessions—for example, lyophilized vaccines, such as measles, mumps, rubella (MMR)—the VVM is fixed to the vial cap or the neck of the ampoule. The VVM can also be fixed to the cap of the mono-dose vials.

Checking the VVM:

- VVM status should be checked at the following times:
 - > VVM status should be checked when vaccines are received at the FDI Warehouse.
 - When vaccines are issued by a store.
 - Check VVM status and expiry dates for each type and batch of vaccine when preparing the issued voucher. Generally, make sure that any vaccine that shows the most VVM exposure is issued first.
 - Immediately before opening the vial, check that the WM status is usable and check that the expiry date has not passed. If both these checks are OK, use the vaccine.
 - If the VVM status is unusable OR the expiry date has passed, **do not** use the vaccine.
 - Put the vaccine to one side until the end of the session and then safely dispose of it.

ANNEX 9- SHAKE TEST PROTOCOL

Vaccine Shake Test

The Shake Test is designed to determine whether aluminum-adsorbed vaccines have been frozen. Whenever it is suspected that vaccine has been frozen, at least one member of the duty personnel in every facility that stores vaccines should know how to perform and interpret the test reliably and correctly. Vaccine that fails the Shake Test should not be distributed or administered.

This annexure explains when to do the Shake Test and what to do if the vaccine has been damaged by freezing. The Shake Test protocol is attached as annex 2; there is only one correct way to conduct this test.

Applicability

The Shake Test currently applies to the following vaccines:

- pentavalent
- pneumococcal
- tetanus toxoid

After freezing, the bonds between the aluminum adsorbent and the antigen in a vaccine are broken. Separated adsorbent tends to form larger, heavier granules that gradually settle at the bottom of the vial when it is shaken. Sedimentation occurs faster in a vaccine vial that has been frozen than in a vaccine vial from the same manufacturer that has never been frozen.

When carried out correctly the Shake Test has been shown to have 100% sensitivity and 100% specificity and 100% positive predictive value.

When and How to Do a Shake Test

If a freeze indicator, or other temperature monitoring device, shows a freeze alarm, or if Store Keeper suspects that freezing has occurred, then the Shake Test must be done to confirm the status of the vaccine. Follow the Shake Test protocol exactly as described in *annex 2*.

Individual batches of vaccine may behave differently from one another. Therefore, the procedure should be repeated with **all** suspect batches.

The Shake Test does **not** need to be conducted under the following circumstances:

- When vaccine vial(s) are frozen solid
- With pentavalent vial(s), after vigorous shaking, it is **impossible** to obtain a homogeneous solution. In such cases, the white lumps or sediment cannot be separated from the walls of the glass vial. This only happens with pentavalent vials if they have been exposed to sub-zero temperatures, but they did not freeze

NOTES:

- 1. There is only one correct way to conduct a Shake Test.
- 2. The test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the Shake Test should be conducted on a random sample of vaccines. However, if more than one lot is in the shipment, the random sample must include a vial taken from each and every lot.

NOTES:

- 1) This protocol must not be altered. There is only one correct way to conduct a Shake Test.
- 2) The test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the Shake Test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.
- 1. Take a vial of vaccine of the same type and batch number and made by the same manufacturer as the vaccine you want to test.
- 2. Clearly mark the vial as "FROZEN."
- 3. Freeze the vial in a freezer, or the freezing compartment of a refrigerator, until the contents are completely solid.
- 4. Let it thaw. Do **NOT** heat it!
- 5. Take your "TEST" vial from the batch that you suspect has been frozen.
- 6. Hold the "FROZEN" vial and the "TEST" vial together in one hand.
- 7. Shake both vials vigorously for 10–15 seconds.
- 8. Place both vials on a flat surface side-by-side and start continuous observation of the vials until test is finished.

(NOTE: If the vials have large labels that conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)

Use an adequate source of light to compare the sedimentation rates between vials.

IF-

9. The TEST vial sediments slower than the FROZEN vial,	10. Sedimentation is similar in both vials OR
THEN,	The TEST vial sediments faster than the FROZEN vial THEN,
11. Use the vaccine batch.	11. <u>Vaccine is damaged</u> : Notify your supervisor. Set aside all affected vaccine in a container marked "DAMAGED VACCINE FOR DISPOSAL– DO NOT USE."
	12. Discard all affected vaccine after you receive permission to do so.
	13. Fill in the Loss/Adjustment Form.

ANNEX 10- ELECTRONIC DEVICE REPORT FORM (SAMPLE)

Reporting ALARM details in international vaccine shipments

A special form has been designed for the purpose of reporting alarm details displayed in electronic devices. This form should ONLY be filled in if any alarms have occurred and should be attached to the Vaccine Arrival Report (VAR). A clear photocopy and/or printed copy of the scanned image of the electronic devices displaying alarm status should be attached to this form.

		F	ELECTRONIC I	DEVICE.	ALARM	REPOR	T FORN	Л			
		\neg			Date	of					\neg
Туре	of Device					Туре	e of Vac	cine			
			Q-Tag 2Plus								
			Syptemp II Of	ИS							
Box	Serial	Time	Elapsed	>=45		>=30 <u>°</u> C 1		>=10			.5 <u>°</u> C 1
3 T	,	,	transit time	Time	<u>C</u> C	Time	<u>о</u> С	Time	<u>о</u> С	Time	<u>o</u> C

ANNEX 11-CONDITIONING FROZEN ICE PACKS

A3.1: What is a conditioned ice pack?

When an ice pack is removed from the ice pack freezer, its temperature may be as low as -20°C. If you use these ice packs immediately, there is a risk that you will damage freeze-sensitive vaccines.

A *conditioned* ice pack is an ice pack that has been left outside the freezer for long enough to stabilize at 0°C. This point is reached when the ice inside the ice pack begins to melt.

A3.2: How do I know when an ice pack is conditioned?

An ice pack is conditioned as soon as the ice core inside the pack is surrounded by a small amount of liquid water. You can check this by shaking the ice pack. If you can feel the ice moving inside the pack, it is fully conditioned. This process takes time—up to 30 minutes or more, depending on the temperature of the room.

A3.3: When should conditioned ice packs be used?

Conditioned ice packs must ALWAYS be used whenever you pack the following freeze-sensitive vaccines in a cold box or vaccine carrier:

- > pentavalent
- PCV-10
- tetanus toxoid

You must also use conditioned ice packs whenever you pack a load of vaccines that contain freeze-sensitive products mixed together with—

- **▶** BCG
- > OPV
- > measles

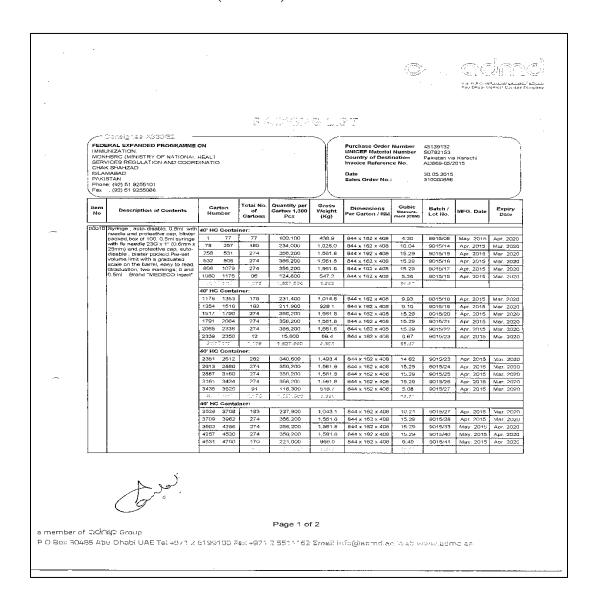
You DO NOT need to use conditioned ice packs when you pack only OPVs.

A3.4: How to condition ice packs

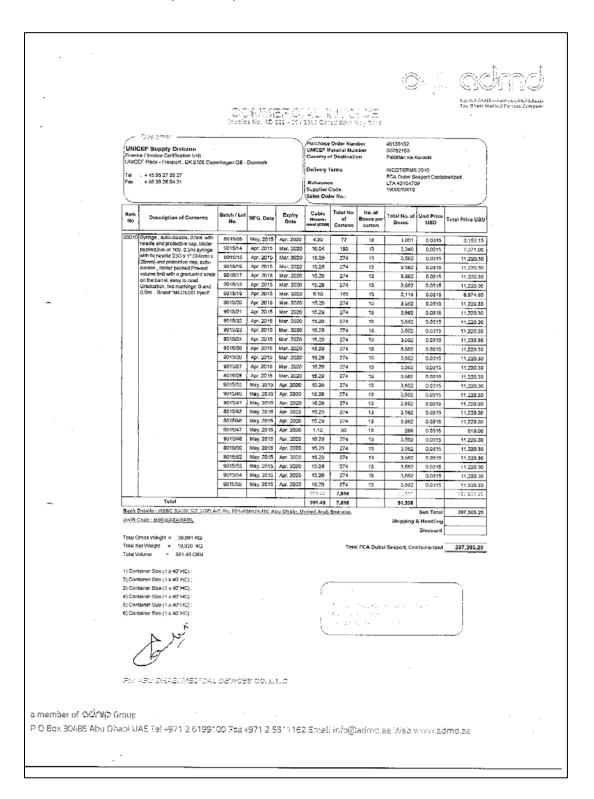
- 1. Calculate how many ice packs are needed for the vaccine consignment. The underside of the lid of the cold box or vaccine carrier usually has a diagram showing the number required for that type of box or carrier.
- 2. Remove the correct number of ice packs from the freezer.
- 3. Lay the ice packs on the designated table or works surface in a single layer leaving a 5 cm space around each pack.
- 4. Check their progress every 10 minutes by shaking a sample of ice packs, as shown below.
- 5. Wait until ALL the ice packs are conditioned; then use them to line the cold boxes and/or vaccine carriers. Pack the vaccine.

DRY STORE

ANNEX 12- PACKING LIST (SAMPLE)



ANNEX 13- INVOICE(SAMPLE)



ANNEX 14- CERTIFICATE OF CONFORMITY (SAMPLE)



Certificate No.: 086/QC/CC/0.5ml/15

CERTIFICATE OF CONFORMITY

This is to certify that...

Product Description : 0.5 ml Auto Disable Syringe (MEDECO INJECT AD)

Needle Size : 23G x 1" (0.60mm X 25mm)

Product Reference No. : SFG-01003 Purchase Order No. : 45139132

Invoice Reference No. : AD 669-05/2015

UNICEF Meterial Number : S0782153

Batch Lot No.	Batch Qty	Sterilization Date	Expiry Date		
9015/18	231,400 Pcs	April 2015	March 2020		
9015/19	211,900 Pcs	April 2015	March 2020		
9015/20	356,200 Pcs	April 2015	March 2020		
9015/21	356,200 Pcs	April 2015	March 2020		
9015/22	356,200 Pcs	April 2015	March 2020		
9015/23	15,600 Pcs	April 2015	March 2020		

Manufacturing/Sterilization : Abu Dhabi Medical Devices Company, LLC

Abu Dhabi, UAE

Sterilization Method : Ethylene Oxide (90% ETO + 10% CO2)

Is sterilized in accordance with ISO Standard 11135-1 for Sterilization of health care productsethylene oxide, Requirements for development, validation and routine control of sterilization process for medical devices and with British Standard for Sterilization of Medical Devices as Requirements for terminally – sterilized devices to be labeled "STERILE", BS EN 556-1:2001. The product is tested in accordance with USP and it has passed the Sterility and Endotoxin Level.

Certified Correct Authorized Person

Sign: Make. / Name: Mohammed Ahmed Ali

Title: QC Section Head Date: May 25, 2015

Markings:

45139132

Customer Ref.: PSS - 115-PAK-04A-X/2015

Pakistan via Karachi

GAVI2015-1115-PAK-04A-X/2015

a member of വാവിറ്റ Group

P O Box 30485 Abu Dhabi UAE Tel +971 2 6199100 Fax +971 2 5511162 Email info@admd.ae Web www.admd.ae

ANNEX 15- PRODUCT ARRIVAL REPORT (SAMPLE)

PRODUCT ARRIVAL REPORT (PAR)

COUNTRY											
REPORT No					Date report	(of				
Place of inspec	ction	Date and tin		Vame tore	of store a	ınd o	date a	ınd tim	e product e	ntered into	
PART I - ADV	ANCE 1	NOTICE	ı								
Date received fax/ email	Date received by fax/ email Pre-advice			Copy Airway Bill (AWB) or Bill of Landing (BOL)			py oice	О	f Copy of Packin List		
	Yes	No 🗌	Yes [No		Ye	s 🔲	No [Yes 🗌	No 🗌	
Other doc requested description)	euments (give								Yes 🗌 N	бо	
PART II - ARI	RIVAL I	DETAILS									
AWB number or	t/ sea port der crossing	vessel of		ETA notifica	as per		per	Actual time of arriva			
BOL number	of dest		Vehic No	Day	Time		Day	Time			

NAME OF	CLEA	RING AGEN	T: _				ON BEHAL	F OF
PART III - I	DETAILS	OF SHIPMEN	VТ					
Procureme nt agency	Purchas Order No.	e Consignee	Proc	duct description	Manu	ıfacturer	Country	
Product deta	uils							
Lot or model number		Number of Num boxes		nber of items		ry date or ma (as applicable	anufacturing e)	
(Please contin	ue overlea	af if necessary)						
Was quantity	received	as per shipping r	notifica	tion?		Yes 🗌	No 🗌	
If not, were	details of	short-shipment p	rovide	d prior to product	arrival?	Yes 🗌	No 🗌	
PART IV - D	OCUME	ENTS ACCOM	PANY	ING THE SHIP	MENT			
Copy of invoice (Copy of packing	opy of packing list		Copy of Certificate of Conformity (where required)		cify)	
Yes No Y		Yes No	es No		Yes No N/A		о	
PART V - GI	ENERAI	CONDITION	OF S	HIPMENT				
What was the arrival?	he condit	ion of boxes or	1					
Were necesshipping box		els attached to)					
Other comm	nents:							

]					
PART VI - NAME AND SIGNATURE									
Authorized Inspection Supervisor Manager DATE	DATE	Primary	— Store	or	FDI				





USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

