

SOP NO: SOP-RELL-0003-CONTROL OF COLD CHAIN GOODS

TITLE

SOP-RELL-0003-CONT ØL ØF COLD CHAIN

GOODS PREPARED BY:Anthony Ekpokoba 9/1/2020

AMPROVED BY CONTROL: Pharmacist Ikwue Olo po DATE: 0/1/2020

EFFECTIVE DATE: 11/1/2020 REVIEW 11/1/202! SUPERSEDES:

DATE:

1. Purpose:

To define the procedures required to maintain the Cold Chain of fridge line items, which have been received from the Vendor, by Rapid Express Logistics Limited (RELL).

2. Scope:

Includes all processes necessary for compliance to temperature specifications for Thermolabile products which have been received by, stored in and distributed from the distribution center.

3. Responsibilities:

Title	Responsibility
Distribution/Warehouse	Processes the orders in such a manner as to ensure that the cold
Manager	chain is maintained.
Materials Handling	Receiving, picking and checking and packing of cold chain
Clerk	products, and completing Fridge Item: Distribution Register
Responsible Pharmacist	Checks and Signs the Cold Chain Product Register, retrieves
	temperature monitoring devices and reports non-conformances
	to Global Inventory Manager.
QA Manager	Performs additional inspections on suspect fridge line items and
	makes decision as to their disposition/ disposal in conjunction
	with the Warehouse Manager.

4. Definitions:

Cold Chain/	Refers to all products which require constant storage between					
Fridge line/	2°Celsius and not exceeding 8° Celsius. This also includes vaccines and					
Thermolabile	other products that require storage at product specific temperatures.					
Fridge Box	A shipper/polystyrene container validated to maintain the cold chain					
	for a specific time period					
Fridge Item	Any item requiring storage between 2 and 8 degrees Celsius.					
Ice Packs / Soft	Specialized packs that can be frozen and can maintain their					
Gel packs	temperature for prolonged periods of time. These need to be frozen					
	before they can be used in the packing of an order. The record of their					
	time frozen needs to be documented in the Ice Pack register.					
Temperature	Monitoring devices that are placed in the shipper(s) with cold chain					
monitoring	products and are record the temperature of goods in transit. Once the					
device	shipment arrives at the destination a designated person removes					
	them from the shipper, reads the data and reports the findings.					

5. Procedures:



5.1 Receiving:

Receiving process shall be based on SOP-RELL-0004-Goods Receiving.

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- 5.2 The Materials Handling Clerk-Receiving shall be responsible for transferring all Cold Chain items to the refrigerator within 5 minutes of Receipt (defined as goods being offloaded from the truck).
- 5.3 The Responsible Pharmacist or designate shall complete all the applicable fields in the Cold Chain Product Register.
- 5.4 The Cold Chain Product Register shall be signed and checked by the Responsible Pharmacist.
- 5.5 Upon receipt into the fridge, the box (s) containing fridge items shall be opened up and removed from the insulating container(s) ensuring all contents are exposed to the Cold Chain conditions and thereafter placed in appropriate locations within the fridge.
- 5.6 **Returns**: Any Thermolabile items returned shall be opened up and removed from the insulating containers ensuring all contents are exposed to the Cold Chain conditions, individually labeled and placed in an appropriate location in a segregated area of the fridge labeled for Returns.
 - If a segregated area is not available, the boxes shall at minimum be clearly labeled as RETURNS and the boxes opened to expose the contents to Cold Chain conditions.
- 5.7 Returns shall be handled as per SOP-RELL-0009-Control of Returned Goods and their storage is the responsibility of the Responsible Pharmacist.
- The Responsible Pharmacist or designate shall check the temperature monitoring devices (for those products that have these included in a shipment); verify that temperatures were maintained between 2-8 degrees Celsius and/or that the delivery was received within the prescribed requirements for the product.
- 5.9 Any temperature monitoring devices shall be checked and/or collected and handled by the Responsible Pharmacist, as per client specific procedures provided to the distribution center.
- 5.10 If a break in the Cold Chain is confirmed or suspected, the Responsible Pharmacist shall inform the QA Manager in writing and await further instruction.
- 5.11 Suspect fridge line items shall be maintained in Cold Chain conditions until instruction is received from the QA Manager, refer to SOP-RELL-00010-Handling of Rejected Goods regarding specifics for the handling of suspect products.

5.12 Order receipt process:

On receipt of an Order containing Cold Chain goods, the Distribution/Warehouse Manager receiving the Order shall process the Order in such a manner as to ensure that fridge line items can be picked, packed and checked within the stipulated time frames to ensure Cold Chain maintenance.

5.13 Picking and Checking Process:

- 5.13.1 When an Order containing a fridge item, is received for picking and checking, the Materials Handling Clerks (Picker and Checker) shall be informed to prepare for the control of Cold Chain goods.
- 5.13.2 The Materials Handling Clerks-Picker shall assemble the order as per SOP-RELL-0011 Picking of Orders, checking the following:
 - Bin Location;

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- Batch numbers;
- Product Description;
- Quantities.
- 5.13.3 The Materials Handling Clerk-Checker shall check the consignment concurrently with the Materials Handling Clerk-Picker so that the time that the product spends out of the cold chain is minimized. Refer to SOP-RELL-0012-Checking and Picking of Orders.
- 5.13.4 The Checker shall pack the Order in a suitable fridge box which has been validated for distribution purposes.
- 5.13.5 Ice packs are not permitted to come into direct contact with the product.
- 5.13.6 Bubble wrap shall be used to protect the product from the ice packs.
- 5.13.7 The product shall be inserted into the appropriately sized box, which is packed with a validated quantity of Gel ice packs and the lid is secured and sealed with tape.
- 5.13.8 The time that the box is sealed and ready for dispatch shall be noted in the Fridge items: Distribution Register by the Materials Handling Clerk.
- 5.14 Dispatch:
- 5.14.1 Cold Chain items shall be distributed using the quickest mode of transport to their destination.
- 5.14.2 Cold Chain items must reach their destination within the shortest time period from dispatch time and date from distribution center to point of delivery.
- 5.14.3 If the Cold Chain is broken during the delivery phase, the Responsible Pharmacist must be informed by the transporter. The QA Manager shall be advised immediately as well.
- 5.14.4 Should any doubt arise as to the maintenance of the Cold Chain at any stage in the distribution process, the Responsible Pharmacist and QA Manager shall be advised of where and how the Cold Chain was broken.
- 5.14.5 The QA Manager shall advise all concerned on the disposition of the products concerned.

7. Records:

- Cold Chain Product Register
- Fridge items: Distribution Register

The records shall be kept for a period not less than 5 years from the date of recording.

8. Distribution:

Regional Distribution Center Management

9. Documents:

Cold Chain Product Register; Attachment: 1

Fridge Item: Distribution Register; Attachment: 1

Fridge line Label. Attachment: 1

10. Amendment History:

Revision:	Effective Date:	Changed By:	Reason:



Dept.:	Warehouse	/Distribution
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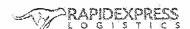
SOP					
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Attachment: 1

Cold Chain Product Register Example

										
Date/Time Dispatched from Vendor (A)	Date/Time Receipt at Warehouse (B)	Time Difference Dispatch/ Receipt (6-A=C)	Time into Fridge (D)	THIS IS A FRIDGE LINE ITEM PLEASE PLACE CONTENTS INTO REFRIGERATOR DIABEDIATELY UPON RECEIPT TO MAINTAIN COLD CHAIN 2°C-8°C		Conit Dev (Y/ corder votteno pro-	ndatie, is inceptable is stronge	Signature Responsible Pharmocisti Branch Manager	Courier Delivery Note Number	
				NO	ITEMS ARE T TO BE FROZEN			2°C-5°Q1		
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	Fridge Items Dispatch Register								
Date	Invoice Number	Time Out of Fridge (A)	Time Box Sealed (B)	Time Difference Fridge/Sealed (B-A)	Time Delivered to Dispatch	Signature of Dispatch Recipient	Area Shipped To		



Dept.: Warehouse/Distribution SOP NO: SOP-RELL-O002-DISPATCH OF ORDERS

TITLE	SOP-RELL-0002-DISPATCH OF ORDERS						
PREPARED BY:	Anthony	Ekpokob	a IV	DATE:	9/1/2020		
APPROVED BY CONTROL:	Pharmacist	lkwue Olokpo	June	BATE:	10/1/2020		
EFFECTIVE DATE:	11/1/2020	REVIEW DATE:	11/1/2025	SUPERSEDES:			

1. Purpose:

To ensure that all Pharmaceutical & Non-Pharmaceutical Health commodities are dispatched in accordance with Good Warehousing and Distribution Practice.

2. Scope:

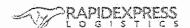
Includes all processes for the dispatch of orders from the Clients ZDC/RDC (Zonal/Regional Distribution Center).

3. Responsibilities:

Title	Responsibility
Distribution/Warehouse	Manages operational dispatch staff, ensures that Security
Manager	personnel perform random spot checks on outbound shipments.
RELL/4PL	Transport company that provides Freight Forwarding services for
	delivery to consignee.

Definitions: 4.

Certificate of	Certificate issued by the Vendor confirming the origin of the
Origin(COO)	product, i.e. where it was manufactured.
Delivery Note	Refers to the document generated by the RDC Warehouse
	Management system that requests the RDC to fulfill an order.
Dispatch	The department responsible for initiating the shipment of goods
	out of the distribution centres.
Dispatch Log Sheet	A log sheet documenting what has been dispatched.
Packing	Refers to the process during which the order is packed into the
	correct sized box or boxes in a manner to prevent damage during
	transit.
Palletized	The consolidation of boxes on a single pallet for shipment.



Pick-slip	Refers to the document generated by the host operating system in response to a Delivery Note, detailing the products and batches to
	be picked for the order.
Shipment Pending	Generated by the update of the ASN indicating readiness of the
for Action Report	shipment for pick-up and delivery to Consignee.
Tax Invoice	A document accompanying a shipment which contains the details
	of the consignee, shipper, products and their prices.
Track and Trace	RELL/4PL's operating system used to keep track of the shipments
System	they are responsible for executing.
Waybill	The document attached to the shipment, supplied by the RELL
	which details the Consignee information, shipping instructions and
	also serves a proof of delivery once the shipment has been
	delivered.

5. References:

SOP-RELL-0003-Control of Cold Chain

6. Procedures:

6.1 Dispatch:

- 6.1.1 The Material Handling Clerk shall place the pallets in the Dispatch Staging area where they will be checked by the Checker.
- 6.1.2 The Distribution/Warehouse Manager, Security and Freight Forwarder shall complete the check list, indicating that everything is in order to allow the shipment to leave the ZDC/RDC.
- 6.1.3 Once checking is completed the checklist shall be provided to the QA Manager to sign.
- 6.1.4 The person signing the checklist shall ensure that the information provided is accurate and a true reflection.
- 6.1.5 The Dispatch Log sheet must be maintained accurately and signed by the Distribution/Warehouse Manager/designate recording every shipment of these products that has been dispatched.
- 6.1.6 The Distribution/Warehouse Manager shall ensure that Security personnel perform random spot checks on goods/shipments received into the Dispatch area. Security personnel shall monitor and conduct surveillance of all areas in the distribution center to ensure that theft and un-authorized transfer of goods is prevented.



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6.1.7 The Material Handling Clerk shall update the status of the shipment in RDC Warehouse Management System.

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- Delivery Note;
- Dispatch Logbook.

These records shall be kept by the Distribution/Warehouse Manager for a period not less than 5 years from the date of recording.

8. Distribution:

Regional Distribution Center Management.

9. Documents:

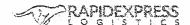
• Dispatch Log Sheet. Attachment 1.

10. Amendment History:

Revision:	Effective Date:	Changed By:	Reason:

Date	Delivery Note Number	No. of Cartons	Product Description	Destination	Checked and Dispatched by:	Security Officer:	Receive d by Driver	Vehicle Reg. No.
							-	
				4				

Attachment 1: Dispatch Log Sheet



SOP NO: SOP-RELL-0005-LOADING & UNLOADING

TITLE	SOP-RELL-0005- LOADING & UN-LOADING OF TRUCKS				
PREPARED BY:	Anthony Ekpokol	ba 🎉		DATE:	9/1/2020
APPROVED BY DIRECTOR:	Pharmacist Ikwu	e Olokpo	1	DATE:	10/1/2020
EFFECTIVE DATE:	11/1/2020 REV DAT	TE: 11/1/2	2025	SUPERSEDES:	

Purpose:

To ensure truck loading and unloading operations of RELL are completed safely and to eliminate the potential for injuries where vehicle and people interaction occurs.

2. Scope:

This procedure applies to all Rapid Express Logistics Limited (RELL) employees, truck operators and other personnel involved in the loading and unloading operations of trucks in the warehouse, service delivery points, wharf, and in any other Port operated areas where loading and unloading of trucks occurs. Cargo types could include cartons, containers, palletized cargo, bulk bags, casing and project cargo.

3. Responsibilities:

i. Distribution Manager

- •Ensure this procedure is developed and reviewed with adequate consultation; and
- Authorizing approval and amendments to this procedure.
- •Implementing this procedure, including education regarding critical changes to the procedure is communicated to RELL supervisors, employees and affiliated 4Pl companies;
- Monitoring compliance with this procedure;
- •Periodic review of this procedure; and

ii. Supervisor/person in charge

- •To ensure they and their team members comply with this procedure;
- •To ensure that the stevedores operating equipment that requires a high risk work license, have a current license and are currently verified as competent to operate the equipment;
- •To ensure the loading and unloading of trucks is conducted safely and in consultation with the truck driver;
- •To ensure adequate and appropriate instructions regarding this procedure are provided to the RELL drivers/loading assistants and relevant third parties in the logistics chain.

iii. Employees

All RELL employees must comply with the following procedures;



- •To follow instructions from the supervisor or person in charge regarding this procedure;
- •To report all hazards and/or incidents to your supervisor as soon as possible
- Employees who are allocated a high risk role on the shift, e.g. crane operation, dogman or rigger, forklift operator is to ensure they currently verified as competent to carry out that task and to follow the requirements of this procedure;
- •The dogman or forklift operator is responsible for confirming with the truck driver:
- -the location of the safe zone;
- -when cargo operations have been completed; and
- -when it is safe to move from the safe zone.

iv. Truck Operators

All RELL truck operators must comply with the following procedures;

- •To report any hazards or incidents to a KPA employee, and
- •To comply with directions from KPA employees in regards to this procedure.
- •To secure loads correctly
- •To ensure that any specific loading requirements are passed on to the supervisor in charge of loading.

4.PPE AND SAFETY EQUIPMENT

All RELL Employees and Port Users are required to wear the minimum PPE requirements. All KPA employees can refer to the KPA PPE SOP for more detailed information.

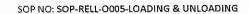
All RELL employees and truck drivers involved in the loading and unloading process must wear appropriate gloves, unless they are operating equipment e.g. crane, truck or forklift. To achieve hands free operations, hands free tools e.g. stiffy sticks are to be used and tag lines where deemed necessary by the supervisor, dogman or crane driver.

Stairs or platforms are to be used to access truck trailer decks when rigging/unrigging loads. Appropriate equipment such as traffic cones, flags and/or bollards, are to be used to mark the exclusion zone around the work area and safe zones. For example, red/orange/yellow traffic cones for work/exclusion zones and green traffic cones for safe zones such as PPE free zones.

5.TRUCK LOADING & UNLOADING PROCEDURES.

The following are general loading and unloading procedures for trucks:

- •Trucks may be loaded and unloaded either manually, by hands, cranes and/or forklifts. The use of crane or forklift is determined by the RELL Distribution Manager/Supervisor/person in charge.
- •Loading/unloading cargo by forklift is to be done by the delegated competent forklift operator utilizing safe zones and work areas as per Forklift SOP.
- •Never stand under the load.
- •RELL employees must not stand on truck trailers during placement or removal of loads by cranes or forklifts. Access to truck trailers should be avoided where possible and only occur with the authorization of the supervisor/person in charge, once the load is landed and settled on the truck and where an adjacent platform, for example a trailer, work platform or stairs, is in place. Stairs need to be controlled by another person while in use.





- •Lifts are to be checked off the manifest and any discrepancies noted. If there is a weight discrepancy, ensure that the appropriate persons are notified, including truck operators who may need to use alternative load restraint.
- •Be aware of pinch points and crush hazards during the loading and unloading process. Keep hands away from cargo and truck trailer during loading and unloading and do not touch the load with your hands while it is moving. Utilizing hands free tools and tag lines for assisting load movement is appropriate.
- •For trucks the unlashing and lashing will be conducted by the RELL truck drivers or RELL representative. All lashing on vehicles is to be in compliance with the load restraint guide.
- •RELL trucks are to arrive and depart the warehouses, SDP's, Port Lands and the jetty with all items suitably restrained by the transport company. If safe to do so, and in agreement with the Supervisor, trucks can move to the lashing zone for restraining of a load.
- •RELL Truck drivers are not to walk into the work area during cargo handling operations unless authorized by a RELL employee.
- RELL Truck drivers must stay in the safe zone, for example next to the cab, until the load has been loaded or unloaded and/or the truck driver has been authorized to leave the safe zone by the RELL dogman or forklift operator.
- •RELL Truck drivers are to remain within their vehicles unless there is an operational requirement to do otherwise.
- •RELL is responsible for determining the appropriate restraint method in line with the load restraint guide and the load placement location on truck. RELL driver's assistants are required to bring to the attention of a truck driver when they believe a load is not restrained in accordance with the Load Restraint Guide. Where you believe an unsafe situation has not been addressed adequately then you are required to notify your Supervisor immediately or elevate your concerns to a Management

representative.

•If trucks are required to reverse at Warehouses, SDP's, Port Lands and/or the jetty, then a spotter is required at all times during the reversing operation. It is the responsibility of the truck driver to arrange the spotter. Reversing alarms must be installed and in good working order on all trucks.



SOP NO: SOP-RELL-0004 RECEIPT OF GOODS

TITLE	SOP-RELL-0004 RECEIPT OF GOODS				
PREPARED BY:	Anthony Ekpo	koba	A .	9/1/2020	
APPROVED BY DIRECTOR:	Pharmacist Ikv	Pharmacist Ikwue			
EFFECTIVE DATE:	11/1/2020	REVIEW DATE:	11/1/2025	REVIEW DATE:	

1. Purpose:

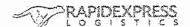
To ensure that all goods received by Rapid Express Logistics Limited (RELL) at any client's warehouse/ZDC/RDC is received, inspected and processed in accordance to the standards set out in this procedure.

2. Scope:

Includes the receipt and inspection of all goods received at any point of delivery and by the distribution centers. It includes medicines, Thermolabile products, test kits, packaging materials and products not readily described as a medicine or a medical device.

3. Responsibilities:

Title	Responsibility
Distribution/Warehouse Manager/Officer	Verifies documentation of incoming orders.
Material Handling Clerk	Offloads and receives the shipment, compiles the GRS and stores the shipment in the allocated bins.
Responsible Pharmacist	Must be involved when damaged stock is received, stock is missing, checks the cold chain register.



4. **Definitions:**

RELL's Delivery Note	A document that is commonly required for a delivery driver to return to his company, the freight forwarder as proof of delivery and inclusion on a trip sheet. It includes the name, date and address. Security staff checks against list of deliveries to permit entry into the distribution centre.
Goods Received	A document created by the receiving department that is used to
Statement (GRS)	inspect the goods upon receipt of a shipment.
Invoice	A Vendor or Client Invoice that accompanies the shipment and
	details the consignee name, address and list of contents and price.
Put Away Label	Or this may be a label which may be generated by hand to identify
	where the stock needs to be put away.
	The transaction in the host operating system that contains the bin
	location and additional product information of which location the
	goods need to be transferred to in the put away process. The hard
	copy of this transaction that is generated is also called the put
	away Label.
Thermolabile products	Refers to all temperature sensitive products, which require
	constant storage at temperatures between 2 and 8 degrees
	Celsius. These products may be referred to as fridge lines or cold chain products

References: 5.

- SOP-RELL-0004-Goods Receiving;
- SOP-RELL-0003-Control of Cold Chain Goods

6. Procedures:

All goods received, including discrepancies if any, shall be processed into the 6.1 Warehouse Management Systems within 24 hours of receipt.



- 6.2 A list of products which require special storage or handling instructions (Thermolabile / narcotic/ psychotropic medicines) shall be available and consulted on receipt of stock.
- On arrival of goods at the Zonal/Regional Distribution Center/SDP, the Site Security or person in charge shall take the Delivery Note/Invoice from the driver and confirm whether or not it is a valid delivery for the ZDC/RDC/SDP.
- 6.4 The site security/person in charge shall hand over the documentation to the Warehouse Manager who will confirm that the consignment is for the ZDC/RDC/SDP.
- 6.6 Security shall then arrange the opening of the Receiving doors in conjunction with the material handling clerk (MHC).
- 6.7 A Materials Handling Clerk (MHC) shall check the inside of the truck for any obvious contaminants and de-dust the box (es) or pallet(s) using a damp cloth before offloading.
- 6.8 A MHC shall then authorize offloading of the consignment, which will be performed by RELL drivers/driving assistant's. If there is a problem with the shipment the Responsible Pharmacist shall be involved.
- 6.9 The quantity of cartons shall be verified against the Invoice before the driver of the delivery vehicle can be released. This is done during offloading by the MHC.
- 6.10 The goods shall be offloaded in the designated Receiving area.
- 6.11 Cognizance shall be taken of the nature of the goods. I.e. Normal goods or Thermolabile, these types of goods shall be processed as outlined in the Special Handling Procedures section of this SOP.
- 6.12 If a shipment arrives and there is damage to the boxes to the extent that the outer carton has been compromised and product is missing, the boxes shall be quarantined. The Pharmacist shall conduct a physical inspection of the entire product to make sure that the security seals are intact, that there is no replacement product in the unit boxes, the overall appearance of the units are as per manufacturer specification.
- 6.13 The MHC shall verify the the following details on the Invoice which is comprised of the following:
 - a. Identity of the goods
 - b. Batch numbers of the goods
 - c. Expiry dates of the goods
 - d. Product code
 - e. Quantity of goods per pallet
 - f. Quantity of goods per shipper/case



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- g. Supplier details
- h. Signature of the person who received the goods.
- Gross condition of the goods. Damages are noted on the GRS at the point of receipt (Damages will be handled as per SOP-RELL-Handling of Rejected Goods).
- 6.15 The MHC shall compare the Goods Received to the Invoice for any discrepancies and compares these with the Purchase Order before confirming the delivery in the distribution center host operating system.
- 6.16 Once the MHC verifies that, there is no discrepancy between the Invoice and the Goods Received, all goods shall be assigned to a pallet.
- 6.17 If any products are received where the condition, inspection or quality is suspect, refer to SOP-RELL-Receipt of damaged stock at the Regional Distribution Centre (RDC) as well as to SOP-RELL Handling of Rejected Goods for specifics on controlling the disposition of damaged, expired or suspect product.
 - The Responsible Pharmacist shall notify the QA Manager;
 - The items shall be placed in the Quarantine area or labeled as such in the absence of a separate area, segregated from other goods as per SOP-RELL-Handling of Rejected Goods.
 - The products shall remain in Quarantine while awaiting further instruction from the QA Manager.
- 6.18 The MHC shall capture the details of the Goods Received in the host operating system to generate a put away transfer order.
- 6.19 The put away transfer order is given to the Receiving Department to move the goods from the Receiving area to the Bin Location allocated on the put away transfer order.
- 6.20 The Receiving Department shall attach a printed put away label to each pallet before physically moving it, this label references the following information:
 - Batch number;
 - Bin location;
 - Date received;
 - Product code;
 - Expiry date;
 - Quantity.





- 6.21 IF a printed label is not available, at minimum the product batch number and bin location shall be hand written on an A4 blank piece of paper which is attached to the pallet.
- 6.23 Before thee goods are physically moved to the bin locations, the Responsible Pharmacist shall ensure that the documentation of the goods received is correct when checked against the Purchase Order and the Invoice. The minimum documentation to be checked includes:
- 6.24 The Responsible Pharmacist shall notify the Receiving Department that goods can be put away.
- 6.25 The Receiving Department shall transfer the palletized goods to the relevant bin locations as indicated on the put away label.
- 6.26 The status of the goods shall be updated in the Warehouse Operating System.
- 6.27 Special handling requirements: Procedure for receipt and storage of specific item types requiring special handling.
- 6.27.1 Cold Chain Goods:
 - On receipt of a shipment of refrigerated items, the Material Handling Clerk shall confirm that the shipment is for the Distribution Center, before authorize offloading of the goods. Refer to SOP-RELL-0003-Cold Chain Management.
- 6.27.2 The Receiving Clerk shall be responsible for transferring all Cold Chain goods to the refrigerator within 5 minutes of Receipt (defined as goods being offloaded from the truck).
- 6.27.3 All fridge line items upon receipt in the fridge shall be opened up and removed from the insulating container ensuring all contents are exposed to the Cold Chain conditions and placed in appropriate locations in the fridge.
- 6.27.4 The Responsible Pharmacist or designate shall complete the Cold Chain Product Register and all applicable fields.
- 6.27.5 The time of receipt **shall be** recorded on the Cold Chain Product Register which is signed and checked by the Responsible Pharmacist.
- 6.27.6 The Responsible Pharmacist or designate shall check that the temperature monitoring devices (for those products that have these included in the shipment) verify that



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temperatures were maintained between 2-8 degrees Celsius and/or that the delivery was received within the prescribed requirements for the product.

- 6.27.7 If temperature monitoring devices are included in the shipment and the data cannot be read at the distribution center, the devices shall be returned to the supplier's QA representative.
- 6.27.8 If a break in the Cold Chain is confirmed or suspected, the Responsible Pharmacist shall inform the QA Manager in writing and await further instruction.

7. Records:

- RELL's Invoice/Delivery Note;
- Cold Chain Register.

8. Distribution:

Regional Distribution Center Management

9. Documents:

Invoice;

Put away Label

Put away Transfer Order

QA Inspection Checklist

Cold Chain Register

10. Amended History:

Revision:	Effective Date:	Changed By:	Reason:

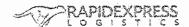


Dept.: Warehouse/Distribution SOP NO: SOP-RELL-0004 RECEIPT OF GOODS

Attachment: 1

Goods Received Statement Example

GOODS RECEIVED	STATEM	ENT	00001					
CUSTOMER				0701-1				
SUPPLIER								
QUARANTINE				G.R.S. DATE				
DUTY PAID				DELIVERY	NOTE No			
				NUMBER	ER OF	BIN	TOTAL QUANTITY	
PRODUCT DESCRIPTION	PRODUCT CODE	BATCH NUMBER	EXPIRY DATE	FULL	ODD	ALLOCATION	PER PALLET	
				CASES	CASE			
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Dept.: Warehouse/Distribution SOP NO: SOP-RELL-0004 RECEIPT OF GOODS

Attachment: 2

Cold Chain Product Register Example

	Cold Chain Product Register									
Date/Time Dispatched from Vendor	Date/Time Receipt at Warehouse	Time Difference Dispatch/ Receipt	Time into Fridge*	Time Difference Receipt/ Fridge	Product Name	Product Condition	Temperat Monitori Device (Y/N)	ing e	Signature	Courier Delivery Note Number
(A)	(B)	(6-A=C)	(D)	(D-B)			if Y and made it with acce product (IC)	ptable	Responsible Pharmacisti Branch Manager	
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"Placement into refrigerator must be within 30 minutes of receipt of Cold Chain item."

TITLE		SOP-RELL-0001-TRANSPORTATION OF PRODUCTS				
				7	DATE:	
PREPARED BY:		Anthony Ek	Anthony Ekpokoba			9/1/2020
APPROVED BY DL:		Pharmacist Ikwue Olokpo			DATE:	10/1/2020
EFFECTIVE DATE:		11/1/2020	REVIEW	11/1/2025	SUPERSEDES:	
	U		DATE:			

1. Purpose:

To formalize the control over goods dispatched to and from warehouses/services delivery points on behalf of the client by Rapid Express Logistics Limited (RELL).

2. Scope:

Includes the procedures that describe the way goods are to be transported to and from the warehouse/service delivery points to maintain the integrity and quality of the goods in transit, until they reach the destination.

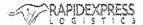
3. Responsibilities:

Responsible:	Ensures that pharmaceutical products are stored and transported
Distribution/Warehouse	in accordance with written procedures
Manager/Officer	

4. Definitions:

Cold Chain Goods	All products, which require constant storage at temperatures between 2 and 8°Celsius. This also includes vaccines and other products, which require storage at product specific temperatures.
Transporter's Delivery note	A document used by the transporter to record once the shipment has been handed over from the distribution center to its driver.
Dispatch Manifest	A document produced by the Warehouse Manager at the distribution center that includes details of daily shipments handed over to the transporter.
Temperature Monitoring Device	Monitoring devices that are placed in the shipper(s) with cold chain products and record the temperature of goods in transit. Once the shipment arrives at the destination a designated, person removes them from the shipper, reads the data and reports the findings.
Transporter	An entity responsible for executing shipments usually by road.
Proof of Delivery (POD)	A document generated by the Freight Forwarder that is signed by the consignee confirming that a shipment has been delivered.

5. References:

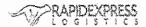


- SOP-RELL-O002-Dispatch of orders;
- SOP-RELL-0003-Control of Cold Chain Goods.

6. Procedure:

Pharmaceutical products shall be stored and transported in accordance with procedures in such a way that:

- The Identity of the product is not lost
- The product does not contaminate and is not contaminated by other products
- · Adequate precautions are taken against spillage, breakage, and theft
- Appropriate temperature and relative humidity conditions are maintained in the case of pharmaceutical products as required, i.e. Cold Chain storage for Thermolabile products and closed vehicles for transport.
- 6.1 The following requirements are to be adhered to by Rapid Express Logistics Limited (RELL) and their affiliated third party contractors:
- 6.1.1 At all times there shall be care in handling of the goods. All consignments are considered to be fragile and shall not be subjected to unnecessary pressure, shock or force.
- 6.1.2 No foreign material shall come into contact with the shipment.
- 6.1.3 The consignment shall be free of dirt, insects or any unhygienic material.
- 6.1.4 The use of closed delivery vehicles which ensure that the shipment is completely covered and protected during transit shall be mandatory (i.e. no pick-up trucks or open vans are to be used). Curtain-sided trucks may be used as long as every precaution is taken to ensure that the products are sealed completely.
- 6.1.5 The consignment shall not be exposed to direct sunlight or excessive heat.
- 6.1.6 The consignment shall not be exposed to adverse weather conditions causing dampness or soiling of the shipment, during transit or while in storage under the supervision of the transporter. This includes storage facilities that belong to the transporter.
- 6.1.7 All cartons leaving the ZDC/RDC shall have a delivery label affixed to it by the ZDC/RDC staff.
- 6.1.8 All the pharmaceutical consignment in our custody shall be traceable at all times during the transit process. (i.e. RELL shall ensure that there is a Track and Trace operating system in each vehicle for identifying status of shipments).



- 6.1.9 Road freight shall be transported in dedicated vehicles; no co-loading or consolidation with non-Regional Distribution Centre goods will be permitted. RELL will provide adequately sized vehicles to ensure that this requirement is adhered to at all times.
- 6.1.10 The temperature requirements for all goods unless otherwise specified shall be less than 25° Celsius and the delivery vehicles shall be appropriately insulated.
- 6.1.11 For Thermolabile goods delivered in cold chain boxes, the delivery time to the client shall not be longer, than the time that the manufacturer and distribution center has validated. The time of the handover from dispatch shall be recorded on the Fridge Item: Distribution Register. In addition, the boxes shall be clearly marked indicating it is a fridge Item. (Reference SOP-RELL-O001-Control of Cold Chain Goods).
- 6.1.12 Prior to loading, the loading section of the vehicle shall be checked by the material handling clerks loading the vehicle to ensure that it is clean and dry and will not damage the goods in any way.
- 6.1.13 The outbound checklist shall be completed and signed by all stakeholders before a shipment leaves the warehouses, and returned to the Distribution Manager/designate who will verify its accuracy and sign it as well.
- 6.1.14 The Responsible Warehouse/Distribution Manager shall update the status of the shipment in the Warehouse Management Information System to "Accepted by RELL" once the transporter has departed with the goods. (Refer to SOP-RELL-O004-Dispatch of orders).
- 6.1.15 The Responsible Distribution Manager/Officer shall complete the dispatch log for every shipment.
- 6.1.16 The minimum information contained in the Dispatch Log is:
 - Dispatch document reference number, date and time;
 - Delivery Note Number;
 - Product name and batch number;
 - Driver's name and signature;
 - Vehicle Registration Number;
 - Quantity of cartons;
 - Consignee;
 - Security Guard name and signature.
- 6.1.17 Following dispatch from the distribution center, RELL shall immediately advise the Operations Manager of any non-compliance to the control of pharmaceutical goods (i.e. any damages from an event that could impact on the integrity or quality of the goods).

- 6.1.18 Any stolen/lost/hijacking or attempted theft of goods shall be immediately reported to their <u>first point of contact</u> who will then contact the Security Coordinator.
- 6.1.19 Upon delivery of the shipment(s), RELL shall ensure that the Waybill/Delivery note is signed and dated. The signed Waybill is the proof that the delivery has been handed over to the Consignee, thereby reflecting the transfer of responsibility and ownership of the shipment to the recipient.

NB: The signed Waybill/Delivery note is the proof of delivery.

- 6.1.20 If there are any problems at the point of delivery, they need to be noted on the Waybill/Delivery Note by the Consignee.
- 6.1.21 RELL shall file the Waybill and ensure that it is retained for reference purposes.
- 6.1.22 RELL shall scan and e-mail a copy of the Waybill to the Regional Distribution Center or to RDC Operations Manager within 48 hrs. of delivery of a shipment. The waybill is part of the Billing pack.
- 6.1.23 RELL shall update their Track and Trace system to reflect that the delivery was completed, including the date, time, and person who signed for the shipment. Any endorsements on the delivery note are also entered and followed up on by the Transporter.

Records:

- RELL Delivery Note/Waybill (copy);
- Dispatch log is kept by the Responsible Pharmacist / Distribution Manager for a period not less than 5 years after the dispatch date;
- Fridge Items: Distribution Register.

8. Distribution:

- Regional Distribution Center;
- Freight Forwarder

9. Amended History:

Revision:	Effective Date:	Changed By:	Reason:
100 100 100 110			