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INTER-FACILITY TRANSFERS OF COVID-19 VACCINES

BACKGROUND

The National COVID-19 vaccine programme includes stakeholders and vaccination sites from both the public and private sectors. The vaccines are procured by the National Department of Health and supplied at zero-value to public sector institutions and at a value to the private sector, stipulated in the letter dated 14 May 2021 from the Director-General: Health. Guarding against wastage of vaccine vials is of critical importance while ensuring equitable and widespread access to vaccines.

As vaccines move through the supply chain and associated storage conditions, the expiry date of these vaccines is shortened. A decline in vaccine demand increases the risk of vials expiring at vaccination sites, and as a result, there is a need to redistribute vaccine vials to sites capable of using the vaccine before expiry. While this often happens within sectors, there is now a need to consider re-distribution between sectors.

The following provides guidance by outlining the process that should be followed during the transfer of COVID-19 vaccines between vaccination sites.

Sites are encouraged, wherever possible, to share vials between sectors on a loan basis to avoid any financial implications in the process.

OBJECTIVE	 To provide guidance on the minimum standards that are required for re-distribution of COVID- 19 Vaccines across health establishments To outline the process for re-distribution of COVID-19 Vaccines across health establishments 		
SCOPE	The scope of the document is limited to the transfer of any COVID-19 vaccines from one site to another, irrespective of the sector.		
COMPILED BY	ORIGINAL DATE:		
AUTHORISED BY			
	Transferring Site means the site which initiates the transaction and provides vaccines to the receiving sites		
	Receiving Site means the site which receives COVID-19 vaccines		
DEFINITIONS	Conditioned Ice Packs means water ice packs that are removed from the fridge/freezer and allowed to remain at room temperature until the ice can be heard to "rattle" in the ice pack.		
	allowed to remain at room temperature until the ice can be heard to "rattle" in the ice pack. Health establishment means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative, or other health services.		

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	National Distributor means the central distributors contracted by the NDoH to warehouse, manage and distribute COVID-19 vaccines on behalf of the department.
ABBREVIATIONS	POD – Proof of Delivery VRT – Vaccine Reimbursement Team WHO – World Health Organisation
 The Treasury regulations (16A3.2) state that a supply chain management system in developed in accordance with the constitutional imperatives for a procurement system is: (a) fair; (b) equitable; (c) transparent; (d) competitive; and (e) cost-effective. Stock transfer is possible under existing policies and government accounting procedua approved by <u>National Treasury: Interdepartmental Transactions and Balances Guerante 2013</u> that sets out the types of engagements between departments in the public sector gives guidelines and recommendations on processes and procedures to be followinitiating, recording and reconciling transfer transactions. Cold chain and Immunisation Operations Manual 	
RELATED SOPs	- Storage and distribution of COVID-19 Vaccines
PRINCIPLES	 Receiving sites which are pharmacies must be recorded in terms of the Pharmacy Act and in possession of a valid Y number and a Section 22(a)15 permit for the provision of COVID-19 vaccination services. Receiving sites which are not pharmacies must have a Section 22(a)15 permit for the provision of COVID-19 vaccination services. The transferring site must collect the information contained in Annexure A, indicating the quantity, expiry date, and batch numbers. The transferring site must identify the receiving site through collaboration with the private sector, province and/or the COVID-19 Vaccine Control Tower and provide the details contained in Annexure A to the receiving site and COVID-19 Vaccine Control Tower. The National Department of Health COVID-19 Vaccine Control Tower must provide details of the transaction to the National Department of Health Vaccine Reimbursement Team (VRT) for approval. Approval will be provided within 2 (two) working days, based on the credit status of either the transferring or receiving sites. The National Distributors must on behalf of the Department, provide details of credit worthiness of the receiving site be behind on its payments to the National Department of Health, the department may put the account on hold across all three distributors and not allow the movement of vaccines to take place. The transferring site is responsible for arranging the transportation costs and inventory risks associated with the movement of the COVID-19 Vaccine between locations. A proof of delivery document, similar to that contained in Annexure B must accompany the delivery.

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10. It is the responsibility of the Transferring site to keep a copy of the signed proof of delivery in support of each transaction. A signed copy of the proof of delivery must be sent to the National Department of Health COVID-19 Vaccine Control Tower once the transfer has been successfully completed.
11. It is the responsibility of the Receiving site to check and verify that the quantity received matches the quantity on the POD (Annexure B) and Annexure A as expected. If the quantity of stock of an item received does not match the quantity on the POD; a detailed note must be made on the Delivery documents and a discrepancy report must be sent to the Transferring site for investigation and correction.
 12. COVID-19 vaccines must be distributed between specific temperature ranges as per the manufacturer's specifications, using appropriate thermal cooler boxes with continuous electronic temperature monitoring devices that monitor the temperature for the delivery duration.
13. The vaccine properties must be considered during distribution. The duration of the journey, transport conditions and temperature profiles of the routes must be known and considered when selecting passive containers and coolant packs.
 13.1.Check the vaccine tray or vaccine vial to ensure the expiry date and time has been updated in line with the temperature at which the vaccine will be distributed. 13.2.Refrigerated state: Vaccines must be placed in prepared passive containers /cooler boxes with conditioned ice packs as per WHO recommendations.
13.3.Electronic temperature monitoring devices must be placed in cooler boxes, and temperature must be maintained within the temperature range appropriate to the vaccine and its expiry date as updated on the packaging.
13.4.The correct type and quantity of coolant/ice packs must be used. WHO does not recommend the use of gel ice/coolant packs.13.5.Vaccine vial trays/vials must not be removed from the refrigerator until the vaccine is
required for distribution. 13.6.Vaccines must be placed upright and securely in the original packaging, or other suitable packaging to protect against light, in the centre of the prepared thermal cooler box.
14. Drug accountability logs must be completed when the vaccine is removed from refrigerator storage and placed in passive containers/cooler boxes preventing the administration of expired/non-usable vaccines to patients.
15. During distribution, vaccines must be handled with care and protected from shocks, drops, and vibration as much as possible.
16. On receipt and before accepting responsibility of the COVID-19 Vaccine transfer, the Receiving site must satisfy itself that no temperature excursions may have happened before or during transfer that renders the COVID-19 Vaccine unusable.
17. If on receipt of the COVID-19 Vaccine transfer the COVID-19 Vaccine is found to have been exposed to temperature variations, the receiving site must not accept the transfer and immediately notify the Transferring site that the shipment will not be accepted.
 The Transferring site will be held financially responsible for the vaccines and will be required to retrieve the vaccine from the Receiving site. A consolidated pack must be sent to the Distributors by the 15th of each month for all COVID-
19 Vaccine vials transferred between sites for the previous period. The pack must contain:

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	19.1. A Summary table of all transfers for the mentioned period		
	19.2. A single zipped file per transfer transaction containing the following supporting		
	documents:		
	19.2.1. Copy of the NDoH approval for the transfer;		
	19.2.2. Copy of the Distributor Invoice/Delivery note on which COVID-19 Vaccing was received reflecting the batch number of the inventory being transferred		
	19.2.3. Copy of the medicine accountability log;		
	19.2.4. Signed copy of the Proof of Delivery;		
	19.2.5. Copy of all temperature records relating to the transfer of the COVID-19 Vaccine and a		
	19.2.6. Copy of the receiving sites Purchase Order for the QTY/Brand being transferred.		
	20. Supporting documents must be kept for a period of 7 years.		
	21. All Credits and re-invoices associated with the COVID-19 Vaccine transfer must be processed		
	by the Distributor before month end and reflect Statement balances due.		
	22. Due to the 90 days' payment terms setup on the Bill To Accounts, the reinvoicing of the vials to the Receiving site will also attract the standard 90-day terms.		
	- COVID-19 Vaccine Control Tower		
FUNCTIONAL	- VRT at NDOH		
ROLES AND	 Responsible Pharmacists (Transferring and Receiving Sites) 		
RESPONSIBILITIES	- National Distributors		
TOOLS/	- Thermal cooler boxes		
MATERIALS/ EQUIPMENT	- Electronic Vaccine Thermometers		

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This p	ocess consists of the following sections:	
1. 2. 3. 4.	Transaction initiation Transaction processing Stock transfer and Receiving process Transaction reconciliation	
Transa	ction Initiation	
1	The Responsible Pharmacist must routinely gather and review information indicating the stock on hand quantity, expiry dates, and batch numbers (Annexure A)	Responsible Pharmacist Transferring Site

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1.2.	For stock that is about to expire, the Responsible Pharmacist must identify the receiving site through collaboration with the private sector, province and/or the COVID-19 Vaccine Control Tower.	Responsible Pharmacist Transferring Site
1.3	Once a receiving site has been identified and is willing to accept the vaccine, the Responsible Pharmacist must provide the details contained in Annexure A to the COVID-19 Vaccine Control Tower.	Responsible Pharmacist Transferring Site
1.4	The Responsible Pharmacist must contact the responsible pharmacist at the receiving site to communicate the information in Annexure A,	Responsible Pharmacist Transferring Site
1.5	The Responsible Pharmacist must obtain a written confirmation from the receiving sites pharmacist that they are willing to accept the vials based on the information provided.	Responsible Pharmacist Transferring Site
1.6	The Responsible Pharmacist must inform the National Department of Health COVID-19 Vaccine Control Tower of the proposed transaction indicating the sending and receiving sites. Include details as filled out in Annexure A and the reason for the transfer.	Responsible Pharmacist Transferring Site
2	Transaction Processing	
2.1	The National Department of Health COVID-19 Vaccine Control Tower must provide details of the transaction as contained in Annexure A to the VRT at the National Department of Health for approval.	COVID-19 Vaccine Control Tower
2.2	The VRT will inform the National Department of Health COVID-19 Vaccine Control Tower of the approval status within two (2) working days.	VRT, NDOH
	Approval will be based on the credit status of either the transferring or receiving sites.	
2.3	The National Department of Health COVID-19 Vaccine Control Tower must advise the transferring site of the approval status within one (1) working day of receipt of the approval	COVID-19 Vaccine Control Tower
2.3.1	If approved, the National Department of Health COVID-19 Vaccine Control Tower must advise the transferring site to proceed with the transaction	COVID-19 Vaccine Control Tower
2.3.2	If not approved, the VRT at the National Department of Health will inform the National Department of Health COVID-19 Vaccine Control Tower to advise the transferring site not to proceed.	VRT,NDOH
	The following are possible reasons why transfers may not be approved	
	Credit status of either the transferring or receiving sites Failure by the Transferring site to practice stack retation	
	 Failure by the Transferring site to practice stock rotation QTY ordered not in line with vaccination capacity stated on EVDS 	
2.4	The receiving site must generate an official Purchase Order (PO) requesting the vials and share this with the transferring site (before receiving the stock) to indicate the	Responsible Pharmacist Receiving Site

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	purchase order number against which the stock is transferred and the details of the stock (as per Annexure A).	
3	Stock Transfer and Receiving Process	
3.1	The transferring site must arrange for the transport of the stock from their site to the receiving site. The transferring site must cover all costs and risk associated with transporting the vaccine to the receiving site.	Responsible Pharmacist Transferring Site
3.2	The transferring site must prepare appropriate thermal containers (passive) and Ice Packs to maintain the vaccine at the appropriate temperature for the distribution of vaccines, pack vaccines in accordance with the relevant SOPs, ensuring that continuous temperature monitoring device(s) are included in the container.	Responsible Pharmacist Transferring Site
3.3	 The transferring site must complete the medicine accountability log (Annexure c), hand over the requisition form, medicine accountability log, proof of delivery document (Annexure B) and packed container to the Courier. The driver must sign the collection form (Annexure D.) The stock must be transported using appropriate cooler boxes with continuous temperature monitoring devices that monitor the temperature for the delivery duration. 	Responsible Pharmacist Transferring Site
3.4	Upon receipt of the stock from the transferring site, the responsible pharmacist should confirm that the stock is in good condition and that no temperature excursions have occurred.	Responsible Pharmacist Transferring Site
3.5	The receiving site must download the data from the logger. If there are no temperature excursions, the pharmacist must accept delivery, complete annexure C and sign off Annexure B	Responsible Pharmacists Receiving Site
3.6	If the receiving site identifies temperature excursions before or during transfer that renders the vaccine unusable, the receiving site must not accept the vaccine and inform transferring site to initiate the return process to the transferring site.	Responsible Pharmacists Receiving Site
4	Transaction Reconciliation	
4.1	No financial transaction reconciliation is required for stock replaced by the receiving site within 30 days in an acceptable condition.	
4.2	If the stock is not to be replaced within 30 days by the receiving site, then the following process must be followed:	
4.2.1	Where the transferring site is a private sector health establishment, and the receiving site is a public sector health establishment:	
4.2.1.1	Send a request to the VRT (cov19vacc <u>transfers@health.gov.za</u>) at the National Department of Health requesting the vaccine distributor (National Distributor) who delivered the initial stock to the private site to credit the transferring site for the amount for the number of vials being transferred and generate a zero-value invoice against the purchase order number provided by the public sector receiving site.	COVID-19 Vaccine Control Tower

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4.2.2	Where the transferring site is a public sector health establishment, and the		
	receiving site is a private sector health establishment:		
4.2.2.1	Send a request to the VRT at the National Department of Health	COVID-19 Vaccine	
	(cov19vacctransfers@health.gov.za) requesting the vaccine distributor (National	Control Tower	
	Distributor) who delivered the initial stock to the public site to credit an amount for the		
	number of vials being transferred at zero-value and generate a priced invoice against		
	the purchase order number provided by the private sector receiving site.		
4.2.3	Where the transferring site is a private sector health establishment, and the		
-	receiving site is a private sector health establishment:		
42.3.1	Send a request to the VRT (cov19vacctransfers@health.gov.za) at the National	COVID-19 Vaccine	
	Department of Health requesting the vaccine distributor (National Distributor) who	Control Tower	
	delivered the stock to the private site to credit an amount for the number of vials being		
	transferred at the original value and generate a priced invoice against the purchase		
	order number provided by the private sector receiving site.		
4.3	Credit Processing		
4.3.1	Upon request by the VRT, the distributor shall process an unlinked credit with unique	National Distributor	
	reference to the documents in Annexure A, B, C and D.		
4.3.2	A Do Not Pick sales transaction must be processed against the unique Purchase Order	National Distributor	
	number of the receiving site		
4.3.3	Reference the credit note number of the receiving site to the sales transaction of the	National Distributor	
	transferring site		
4.4	On receipt of the proof of delivery and proof of approval from VRT at the National	National Distributor	
	Department of Health, the vaccine distributors must execute relevant transactions and		
	provide the sites with the appropriate documents (credit notes and invoices) within five		
	days and reflect the transactions on statements by the close of the		

ANNEXURES	Annexure A: Vaccine Stock Transfer Initiation Document Annexure B: Proof of Delivery Document Annexure C: Drug Accountability Log Annexure D: Collection Form Annexure E: Minimum Information Requirements for Reconciliation of Vaccine Transfers
	Annexure E: Minimum Information Requirements for Reconciliation of Vaccine Transfers

1. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

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TRAINING REQUIRED Training to be conducted post SOP sign-off and prior to the effective date as per above				
Training to be provided to relevant responsible parties after each SOP revision				
Trainees Type of training				

2. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			

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Annexure A

Vaccine Stock Transfer Initiation Document - VST_ID00X

TRANSFERRING SITE

Vaccine Type (Pfizer OR J&J)	Batch Number	Expiry date	Distributor invoice number	Full trays	Partial trays		Current storage temperature	Date moved to current storage temperature
				Number of full trays Pfizer tray = 195 vials J&J tray = 480 vials	Number of partial trays	Total Vials in partial trays		
J&J	Batch123	30 Mar 23	12345678	5	2	460	-20 degrees	
			98765432		1	400	2-8 degrees	21/11/2021
Pfizer	Batch456	15 Jun 22	12121212	10			-20 degree	10/11/2021

Reasons for transfer:

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Annexure B

Vaccine Stock Transfer Proof of Delivery – VST_POD 00X

TRANSFERRING SITE		RECEIVING SITE	
Site name:		Site name:	
MFL code		MFL code	
Bill to Account Number:		Bill to Account Number:	
Contact person:		Contact person:	
Contact number:		Contact number:	
Contact email:		Contact email:	

Vaccine Type (Pfizer OR J&J)	Batch Number	Expiry date	Full trays	Partial tray	Partial trays		Date moved to current storage temperature
			Number of full trays Pfizer tray = 195 vials J&J tray = 480 vials	Number of partial trays	Total Vials in partial trays		
J&J	Batch123	30 Mar 23	5	2 460		-20 degrees	
				1 400		2-8 degrees	21/11/2021

This confirms that the above contents were received in good condition and within the required temperature range as indicated on the temperature logger that accompanied the delivery.

Received by :	_Signature :
Received date :	_Time :
Temperature logger reading :	

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Annexure C

Drug Accountability Log for Re-Distribution of Comirnaty® COVID-19 Vaccines – DAC_000X

Transf	erring Site:		Receiving Site:				
Storag	e Location:	Lot/Batch Number:	Storage Temperature:	Manufacturer's Expiry Date:			
Name a	and Signature of Distributin	g Pharmacist/Vaccine Controller:					
	and Signature of Manager:						
Notes:							
original For ref r The ma	expiry date., where after the rigerator (2-8°C storage): E nufacturer's expiry date and Y DATE les:	n (-80°C to -60°C) to -20°C freezer, vial vaccine should be stored at 2-8°C. xpiry date is 31 days from date the vaccine freezing expiry date should be replaced by eccived from supplier at -80°C to -60°C a	es were taken out of deep-freeze conditio a revised expiry date which MAY NOT	ns (-80°C or -15°C)			
		eezer by 26 May 2021 at 9am. This is the					
2.	Comirnaty® vaccine was re June 2021 at 9am.	eceived from supplier at -80°C to -60°C an	d <u>placed in the fridge at 2-8°C</u> on 12 May	2021 at 9am; therefore, expiry date is 12			
3.	Comirnaty® vaccine was re 25/6/2021 and example 2:	eceived from Distributing Pharmacy in a Th 12/6/2021.	ermal Cooler Box: Expiry date of first defi	rosting applies, i.e., in case of example 1:			
	date must be written in the fo rated storage time starts dire	rmat 12/06/2021: 9am ctly upon removal from frozen conditions.	Once removed from freezing, vaccines m	ay not be refrozen			

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					To be c controller/pha	completed b armacist assist			
	Date DD/MM/YYYY (e.g. 17/04/21)	Time when vials were placed in Thermal Cooler Box (e.g. 9h00)	Number of Vials placed in the Thermal Cooler Box	Temp (⁰C)	Time when vials were removed from the Thermal Cooler Box	Number of Vials removed from the Thermal Cooler Box	Expiry Date Label present on outer carton (Yes/No)	Temp (⁰C)	Comments
1									
2									
3									
4									
5									
6									
7									
8									

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Annexure D

Vaccine Stock Transfer Collection Form – VST_CF00X

Receiving Site:	
Transferring Site:	
Date when Thermal Cooler Box was Handed to Courier	
Number of Thermal Cooler Boxes Handed to Courier:	
Quantity of Vials in Thermal Cooler Boxes	
Name of Pharmacist that handed over the Thermal Cooler Boxes	Signature:
Name of Driver:	Signature:

Notes to Drivers

The Thermal Cooler Box must be placed in the cooler area of vehicle (and not in the trunk of vehicle)

The temperature within the vehicle should not be outside room temperature 15°C to 20°C.

Ensure that the Thermal Cooler Box and envelope of documents is securely placed and is not able to move around.

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Annexure E

Minimum Information Requirements for Reconciliation of Vaccine Transfers

Transferring Site			Receiving Site			Vaccine Transfer Details					
Name	MFL Code	Bill to Acc	Name	MFL Code	Bill to Acc	Batch No	Quantity Transferred	Original Inv No	Transfer PO No	Date Transferred	Transfer POD No

