
 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Disposal of COVID19 Vaccines	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – DISPOSAL OF EXPIRED, OBSOLETE AND UNUSABLE COVID-19 VACCINES


INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Disposal of COVID-19 Vaccines		
OBJECTIVE	To ensure that: <ul style="list-style-type: none"> • Disposal of COVID-19 vaccines at vaccination sites is done in accordance with applicable legislation, including Regulation 44 of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965. • COVID 19 vaccines are disposed in such a manner that they cannot be retrieved: and • The disposal method used minimises any risk to public health and the environment. 		
SCOPE	<ul style="list-style-type: none"> • Disposal of expired, obsolete and unusable COVID 19 vaccines 		
COMPILED BY		ORIGINAL DATE:	
AUTHORISED BY			
DEFINITIONS	<ul style="list-style-type: none"> • Vaccine waste means expired, unused, unusable, spilt, and contaminated pharmaceutical products and vaccines that are no longer required and need to be disposed of appropriately. • Contractor means the waste management company contracted to destroy medicines on behalf of the health establishment/organisation providing vaccination services. • Disposal means the removal of vaccines destined for destruction without the intention of retrieval, in compliance with existing legislation. • Expiry Date means the date up to which a medicine will retain the strength and other properties as stated on the label. • Vaccine Champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist's assistant or nurse and may also function as the vaccination site manager, or as a vaccinator • Vaccine controller means a pharmacist or pharmacist's assistant or other health care professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, outreach sites and/or the supply of vaccines to mobile teams (where applicable) and the updating of data on the Stock Visibility System (SVS). 		
ABBREVIATIONS	<ul style="list-style-type: none"> • NDOH: National Department of Health • SVS: Stock Visibility System 		
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> • Provincial medicine supply management policy and/or supply chain prescripts (as applicable) • Pharmacy Act 53 of 1974 • Medicines and Related Substances Act 101 of 1965 • Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 • National Environmental Management: Waste Act 59 of 2008 • National Environmental Management Act 107 of 1998 		

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	<ul style="list-style-type: none"> Hazardous Substances Act 15 of 1973 Public Finance Management Act 1 of 1999
RELATED SOPs	<ul style="list-style-type: none"> Receipt of vaccines Vaccination Process
PRINCIPLES	<ul style="list-style-type: none"> Adhere to the FIFO/FEFO principles to avoid unnecessary wastage. Always ensure vaccines are kept with the required temperature restrictions Vials with unused doses must be discarded at the end of a vaccination session. Never transport or return opened multidose vials used in vaccination to the cold chain – discard them. A medicine or scheduled substance must only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008). COVID 19 vaccines must not be disposed of into municipal sewage systems or in refuse that is destined for landfill or refuse sites. All vaccines and any other medicines which fall into Schedules 0 - 4 must be destroyed at a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008) and such destruction must be certified as determined by the South African Health Products Regulatory Authority (SAHPRA). All expired, obsolete, unusable, and COVID 19 vaccines must be quarantined in a secure, designated area in the refrigerator/freezer/cold room. Disposal of the vaccines must take place after approval by the responsible pharmacist and/or vaccination site manager.
FUNCTIONAL ROLES AND RESPONSIBILITIES	<ul style="list-style-type: none"> Vaccine controller Vaccinator
TOOLS/ MATERIALS/ EQUIPMENT	<ul style="list-style-type: none"> Biohazard Bins COVID 19 waste disposal form Stock Visibility System (SVS) Electronic Stock Management System/Stock Cards (as applicable)
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	<ul style="list-style-type: none"> KPIs TBD
RECORD KEEPING	- COVID-19 vaccine related records must be kept for a period of five years

1.1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
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<p>This Standard Operating Procedure (SOP) consists of the following sections:</p> <ol style="list-style-type: none"> Confirmation of vaccine for disposal Updating of stock management systems Completion of waste disposal form Filling of biohazard containers Labelling, sealing of biohazard containers and sending to 'mother' health establishment 		
1	Confirmation of Vaccines for Disposal	
1.1	Check if any vaccine vials have reached their expiry date, or the date of expiry assigned for the temperature at which they have been stored (refer Annexure 02)	Vaccine Champion or Vaccine Controller
1.2	In the case of vaccines that require reconstitution check records and confirm if more than six hours has elapsed since reconstitution of vaccine.	Vaccine Champion
1.3	Check for any damaged vaccine vials.	Vaccine Champion
1.4	Identify any vaccine vials with leftover doses of vaccine (whether compromised or not)	Vaccine Champion
1.5	Confirm disposal of vaccine vials: <ol style="list-style-type: none"> Verbally Send email confirming disposal of vaccine vials to vaccination controller. 	Vaccine Champion
2	Updating of Stock Management Systems	
2.1	Capture quantity of disposed COVID-19 vaccine vials on SVS. If applicable, capture quantity of vaccine vials disposed on ESMS or bin cards and where applicable, indicating reasons for disposal.	Vaccine Champion or Vaccine controller
2.2	Subtract disposed quantity from stock on hand and mark stock on hand in red (applicable to manual systems)	
3	Completion of Waste Disposal Form	
3.1	Complete the following information on two copies of waste disposal form (Annexure 4). <ol style="list-style-type: none"> Date Vaccine brand Quantity disposed. Reasons for disposal Specify number of disposals bin Disposed by 	Vaccine Champion or Vaccine controller
3.2	File one copy of waste disposal form.	Vaccine controller
4	Filling of Biohazard Containers	
4.1	Remove unpunctured vaccine vials from outer boxes (where applicable) and dispose of vials in biohazard containers.	Vaccine controller
4.2	Use a permanent black marker to deface the label of all vaccine vials, and empty vial packaging (where applicable), before discarding.	Vaccinator or Vaccine champion or Vaccine controller

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	Alternatively remove the label of the empty vial, tear it in two and discard the label appropriately.	
4.3	Store other copy of waste disposal form with a biohazard container.	Vaccine champion or Vaccine controller
5	Labelling; Sealing of Biohazard Containers and Sending to 'Mother' Health Establishment	
5.1	Ensure that the biohazard container is filled to correct level.	Vaccine controller
5.2	Permanently seal the biohazard container to prevent reopening of the container.	
5.3	Label biohazard container with a structured sequence number for traceable purposes.	
5.4	Send filled biohazard container to the 'mother' health establishment (primary vaccination site) with copies of completed of waste disposal forms for collection by the contractor.	Vaccine controller

ANNEXURES	Annexure 1: COVID 19 Vaccine Disposal Form
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2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved


TRAINING REQUIRED

- Training to be conducted post SOP sign-off and prior to the effective date as per above
- Training to be administered to relevant responsible parties after each SOP revision

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			
Approved by			

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Annexure 1: COVID 19 Vaccine Disposal Form

COVID 19 VACCINE DISPOSAL FORM

Name of Facility:
District

Vaccine	Unit of issue (Vials/Syringes)	Quantity of Vials/syringes	Expiry Date	Batch Number	Reason for Disposal
Janssen COVID 19 Vaccine					
Comirnaty® COVID-19 Vaccines					

Name of Pharmacist who approved Disposal of Vaccines: _____

Signature of Supervisory Pharmacist: _____

From (Name of Hospital/CHC) _____

Telephone Number: _____

Name of Vaccine Controller: _____

Signature of Vaccine Controller: _____