STANDARD OPERATING PROCEDURES FOR MANAGEMENT OF ESSENTIAL VETERINARY SUPLIES SYSTEM (EVSS)

Document Approval

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Contents

DEFINITIONS AND ABBREVIATIONS

Adverse Drug Reaction (ADR): A response to a veterinary medicinal product that is noxious and unintended and occurs at doses normally used in animals.

Adverse Event (AE): Any untoward medical occurrence in an animal temporally associated with the use of a veterinary medicinal product, whether considered related to the product.

AHD: It refers to Animal Health Division

Authorized Personnel: Veterinary professionals with the legal authority to prescribe and administer controlled drugs.

Awardee: It refers to the individual who is awarded the tender.

BFDA: It refers to the Bhutan Food and Drug Authority**.**

Cas: It refers the Centre Agencies

CFs: It refers the Central Farms

Consignments: It refers to newly arrived medicines, non-drug items and veterinary equipment in the store.

Controlled Drugs: Drugs that have the potential for abuse and are subject to legal restrictions. This may include narcotics, psychotropic drugs, and other drugs with potential for human misuse.

Database: It refers toa collection of electronic information that is organized so that it can easily be accessed, managed, and updated.

Direct procurement: It refers to procurement of identified items wherein normal procurement formalities can be exempted, and the procurement is to be made directly from the distributor/manufacturer after obtaining approval from relevant authorities.

Dispensing Register: It refers to a register to record medicines/non-medicines dispensed for use.

Distribution List: It refers the indented list of medicines, equipment and consumables which is approved by DVEU as per the stock at LCS

Distribution order: It refers to official letter signed by program director of NCAH for distribution of medicines, equipment and consumables to respective dzongkhags/agencies.

DLO: It refers to Dzongkhag Livestock Office.

DoL: It refers to the Department of Livestock.

Double Lock System: A secure storage system with two separate locks requiring two different individuals to access the drugs.

DRA: It refers to Drug Regulatory Authority.

DVEU: It refers to Drugs, Vaccine & Equipment Unit, NCAH, Serbithang

DVH: It refers to District Veterinary Hospital.

DVH: It refers to Dzongkhag Veterinary Hospital.

Effective Date: It refers to the date that a document becomes effective for use.

e-GP - It refers to the electronic government procurement system

Emergency requisition: Those medicines that are immediately required and faced acute shortage in the field and not included in normal distribution cycle.

EVDP Focal: It refers to the person who is identified and appointed at Regional and dzongkhag levels to carry out activities related to EVDP as defined by EVDP-TOR.

EVDP: It refers Essential Veterinary Drug Program.

Goods: It refers to medicines, non-drug items and veterinary equipment.

Hazardous Waste: Waste that poses a significant risk to human health or the environment, such as chemicals and certain pharmaceuticals.

Identified items: It refers to the veterinary medicines, vaccines, consumables and hospital equipment required during an emergency outbreak or for those items unquoted in the tender.

Infectious Waste: Any waste that is likely to contain infectious agents, such as animal carcasses, tissues, and body fluids.

Inspection: It refers to careful examination of medicines, non-drug items and veterinary equipment.

LCS: It refers to the Livestock Central Store, Phuntsholing

LECs: It refers the livestock extension centers

Medicines: It refers to all kind of drugs for use in animals.

MoAL - It refers to the Ministry of Agriculture and Livestock

MoF - It refers to the Ministry of Finance.

MPD- It refers to the Medical Product Division.

NCAH: It refers to the National Center for Animal Health, Serbithang.

NDAs: It refers the Non-Departmental Agencies

Non-medicines: It refers to consumables such as instruments, cottons, bandages etc for use at the hospital.

NVH: It refers to National Veterinary Hospital

PA Admin.- It refers to the Procurement Agency Administrator.

Para veterinarian: It refers to a person with a diploma in Animal Science and is authorized to provide treatment to the animals.

Pharmacovigilance: The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related [1] problem.

PRR - It refers to the procurement rules and regulations

Quarantine: It refers to a place of isolation in which medicines; non-drug items and veterinary equipment that have arrived to centers are placed.

RLDC: It refers the Regional Livestock Development Centre

RNR-EC: it refers to the Renewable Natural Resources Extension Center

RVH & EC: It refers to Thromde Veterinary Hospital/Regional Veterinary Hospital & Epidemiology Centre

RVH-EC: Regional veterinary hospital and epidemiology center.

Serious Adverse Event (SAE): An adverse event that results in death, is life-threatening, results in significant disability/incapacity, requires prolonged hospitalization, or is a congenital anomaly/birth defect.

Sharps: Any object that can puncture or cut the skin, such as needles, syringes, scalpels, and broken glass.

Signal: Information suggesting a possible causal relationship between a medicinal product and an adverse event, previously unknown or incompletely documented.

Stock Register: It is a register to record medicines, non-drug items and veterinary equipment with respect to quantity received, issued, cost, batch numbers and expiry dates.

TEC: It refers to the Tender Evaluation Committee.

Veterinarian: it refers to a person with a qualification in B.V.Sc. and AH/DVM

Veterinary Paraprofessional: It refers to a person with diploma in Animal Science and is authorized to provide treatment to the animals

VHs: It refers to veterinary hospitals in the country.

VMPW: Veterinary Medical and Pharmaceutical Waste.

1. SOP for Annual Indenting of Veterinary Medicines, Vaccines, Equipment and Consumables

1.1 Purpose

This SOP describes the procedure for annual requisition/indenting of veterinary medicines, vaccines, consumables, and equipment for annual procurement by the National Center for Animal Health.

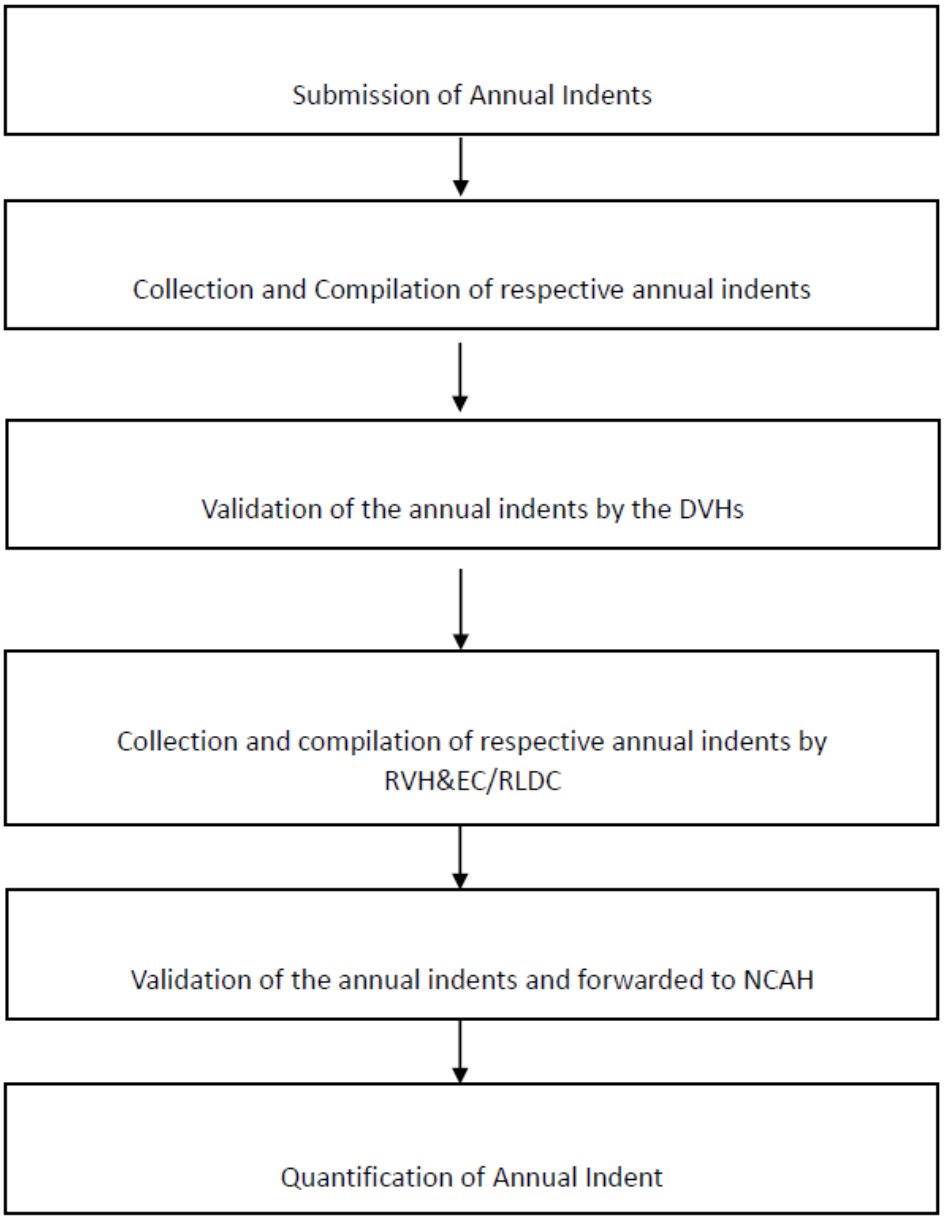
1.2 Scope

This SOP is applicable to the institutions involved in annual requisition/indenting of veterinary medicines, vaccines, consumables, and equipment.

1.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1.	LECs/CAs/CFs/NDAs	1. Prepare & submit the respective annual indent to respective DVHs/RLDC/RVH&EC
2.	DVH	1. Compile the indents received from the LECs. 2. Review and validate the indent submitted. 3. Submit the compiled indents to the respective RLDC/RVH&EC
3.	NVH/RLDC/RVH&EC	1. NVH Prepare and submit directly to DVEU 2. RLDC/RVH&EC compile the indents received from the DVHs/CAs/CFs 3. Review and validate the indents submitted. 4. Forward the compiled indents to NCAH
4.	DVEU/NCAH	1. Quantification of Annual Indent

1.4 Process flow



1.5 Procedure

1.5.1 LECs/CAs/CFs/NDAs

	SOP for Management of Essential Veterinary Drug Program			
	Document Number	Effective Date	Review Date	Version No
				001

1.5.1.1 Preparation of annual indent by LECs as per the usage pattern or trend/cattle population/disease outbreak in the previous fiscal year and submit to respective DVH
1.5.1.2 Preparation of annual indent by CAs and CFs as per the usage pattern or trend/cattle population/disease outbreak in the previous fiscal year and submit to RLDC/RVH&ECs
1.5.1.3 Preparation of annual indent by NDAs as per the usage pattern or trend/cattle population/disease outbreak in the previous fiscal year and submit to NCAH.

1.5.2 DVH
1.5.2.1 Collect the respective annual indents submitted by the respective LECs in the district
1.5.2.2 Review and validate the indent submitted
1.5.2.3 Compile the annual indents and prepare the collective indent for the district and forward to respective RLDC/RVH&ECs

1.5.3 RLDC/RVH&EC
1.5.3.1 Collect the respective annual indents submitted by DVHs/CAs/CFs in the region
1.5.3.2 Review and validate the indent submitted
1.5.3.3 Compile the annual indents of the region and forwarded to NCAH

1.5.4 DVEU/NCAH
1.5.4.1 Receive the annual indents
1.5.4.2 Collect the respective annual indents submitted by DVHs/CAs/CFs/NDAs under Gasa, Punakha,Wangdue,Thimphu, Paro and Haa Dzongkhag
1.5.4.3 Quantification and preparation of the national indent for procurement

1.6 Related Forms or Work Instructions
1.6.1 Prescription form.
1.6.2 SOP for Disposal of Pharmaceutical and Biological waste.

1.7 References
1.7.1 SOP on SOP format – Drug Regulatory Authority, Thimphu.
1.7.2 Management Sciences for Health 2012 – Medical stores Management. Good Pharmacy Practice (GPP) in Developing Countries: Recommendations for Step-wise Implementation.

2. SOP for Tender Process of Medicines, Vaccines, Consumables & Equipment

2.1 Purpose

	SOP for Management of Essential Veterinary Drug Program			
	Document Number	Effective Date	Review Date	Version No
				001

This SOP describes the procedure for annual tender of veterinary medicines, vaccines, consumables and equipment by the National Center for Animal Health.

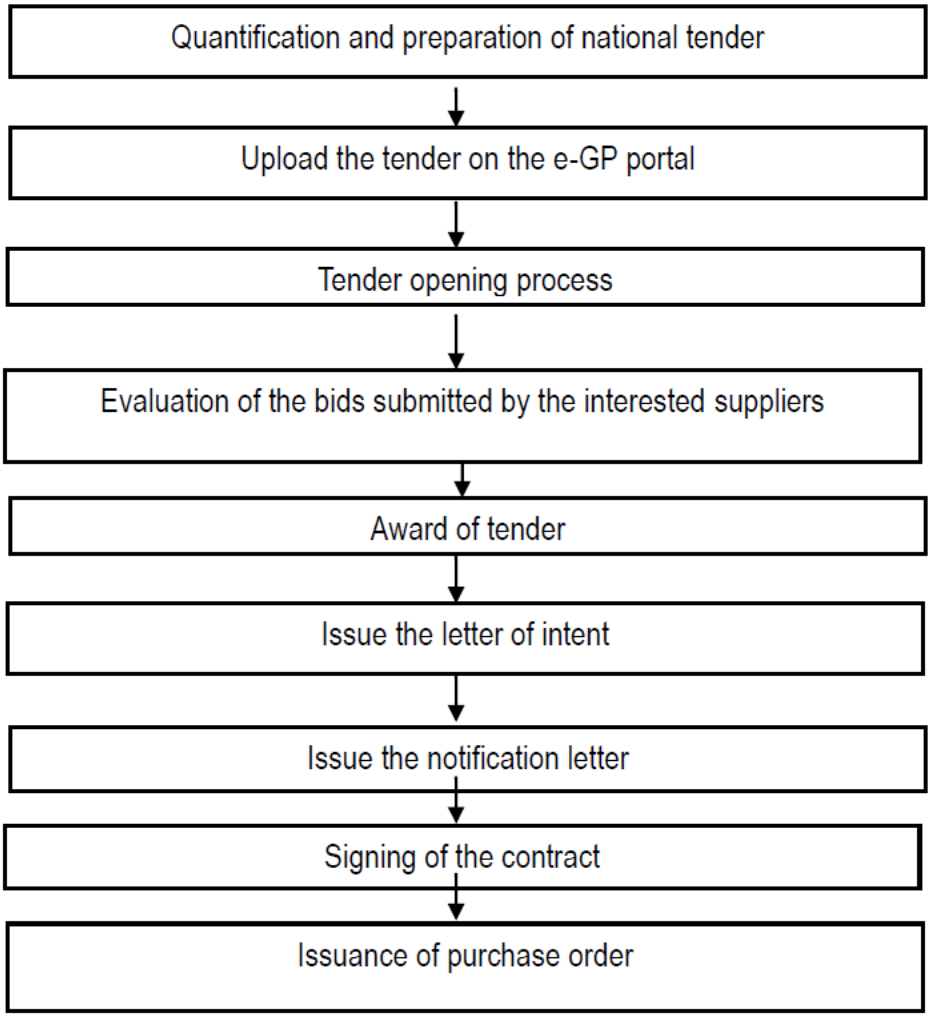
2.2 Scope

This SOP is applicable to DVEU/NCAH for Veterinary Medicines, Vaccines, Consumables and Equipment.

2.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1.	DVEU, NCAH	1 Quantification of the medicine, vaccines, consumables and equipment as per Indent 2 Preparation of tender documents 3 To initiate the procurement process (uploading of tender in e-GP portal)
2	NCAH PA admin/Tender Opening Committee/	1. Refer section 3.1.3 PRR 2023
3.	Tender evaluation committee	1. Refer section 3.1.4 of PRR 2023
4.	Tender awarding committee/ Tender committee	1. Refer section 3.1.2.3 of PRR 2023

2.4 Process Map in Flow Chart



2.5 Procedure

2.5.1 Preparation of national tender based on the finalized and endorsed annual indent for the fiscal year.
2.5.2 Publish/advertising the tender on e-GP portal
2.5.3 Tender opening
2.5.4 Evaluation of the bids raised by the supplier for the tender
2.5.5 Award of tender to the awardee
2.5.6 Issue the letter of intent to all the bidders. The Letter of intent is sent automatically by the e-GP system after accepting the evaluation by the chair of TEC.
2.5.7 Intimate the unsuccessful bidders with the decision made by the tender committee.

2.5.8 Maintain a period of 5 days as stand still period wherein the suppliers may lodge complaint to the decision made by the tender committee.
2.5.9 Issuance of letter of acceptance to awardee
2.5.10 The contract between the procurement agency and the awardee is signed within 15 days after the letter of acceptance has been issued.
2.5.11 Issuance of supply order to the awardee in 5 days for one-time purchases.

2.6 Related Forms or Work Instructions

2.6.1 Qualification Criteria for Registration or Prequalification 2.1.3 of 2023
2.6.2 Sample format for letter of intent - e-GP system
2.6.3 Sample format for letter of acceptance - Standard Bidding Document 2015, MOF

2.7 References

2.7.1 Procurement Rules & Regulations 2023

3. SOP for Direct Procurement of Veterinary Medicines, Vaccines, Equipment and Consumables

3.1 Purpose

This SOP describes the procedure for direct procurement of identified items during the time of an emergency or for unquoted identified items after the tender.

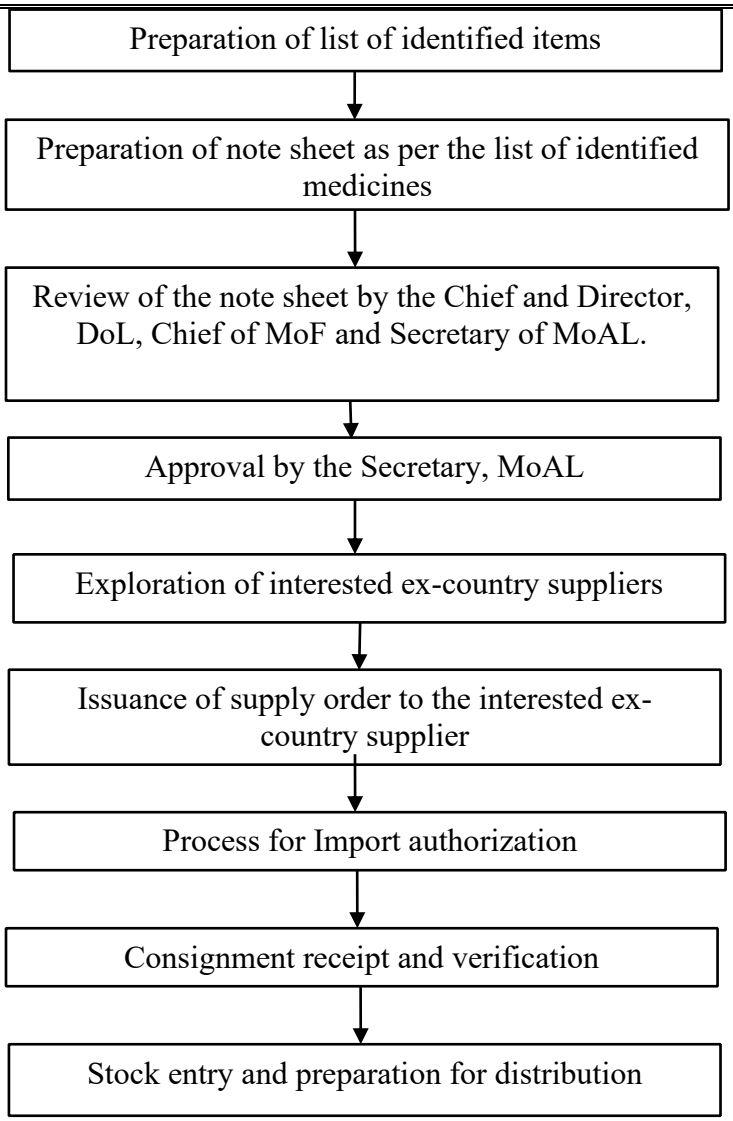
3.2 Scope

This SOP is applicable for veterinary medicines and vaccines, consumables, and equipment.

3.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1.	DVEU, NCAH	• Preparation of note sheet of direct procurement based on the invoice • Obtaining approval for procurement from the relevant authority • Explore the interested distributor/manufacturer ex-country • Placing supply order after seeking approval • Team formation for the procurement to procure from nearby Indian market if required • Preparation of letter for issuance of import authorization • Develop the list of identified items for direct procurement
2	Chief, AHD, DoL	• To review, sign and forward the note sheet of direct procurement to Director, DoL
3.	Director, DoL	• To review, sign and forward note sheet of direct procurement to MoF
4.	Chief, Cluste Finance, MoF	• To review the note sheet of direct procurement
5.	Secretary, MoAL	• To review and approve the note sheet of direct procurement received after verification from the MoF
6.	MPD/BFDA	• Review the letter • Issuance of Import authorization

3.4 Process Map in Flow Chart



3.5 Procedure

3.5.1 Preparation of the list of identified items for direct procurement by DVEU/NCAH.
3.5.2 Preparation of note sheet of direct procurement for approval
3.5.3 The note sheet is sent for review and endorsement by the Chief and Director of DoL, Chief of Cluster Finance, MoF and finally approved by the Secretary of the MoAL.
3.5.4 After seeking approval, explore the ex-country distributor/manufacturer through correspondence or site visit if required.

3.5.5 Select the items that are available
3.5.6 Placing supply order or procure onsite
3.5.7 Process for import authorization from MPD/BFDA
3.5.8 Consignment receipt at LCS
3.5.9 Verification of the consignments
3.5.10 Stock entry, storage and prepare for distribution

3.6 Related Forms or Work Instructions
Nil

3.7 References
Nil

4. SOP for Receiving Consignment of Medicines, Vaccines, Consumables & Equipment

4.1 Purpose
This SOP describes the procedure for receiving the consignment at LCS/NVH/RVH&EC/RLDC/DVH/RNR-EC/CF

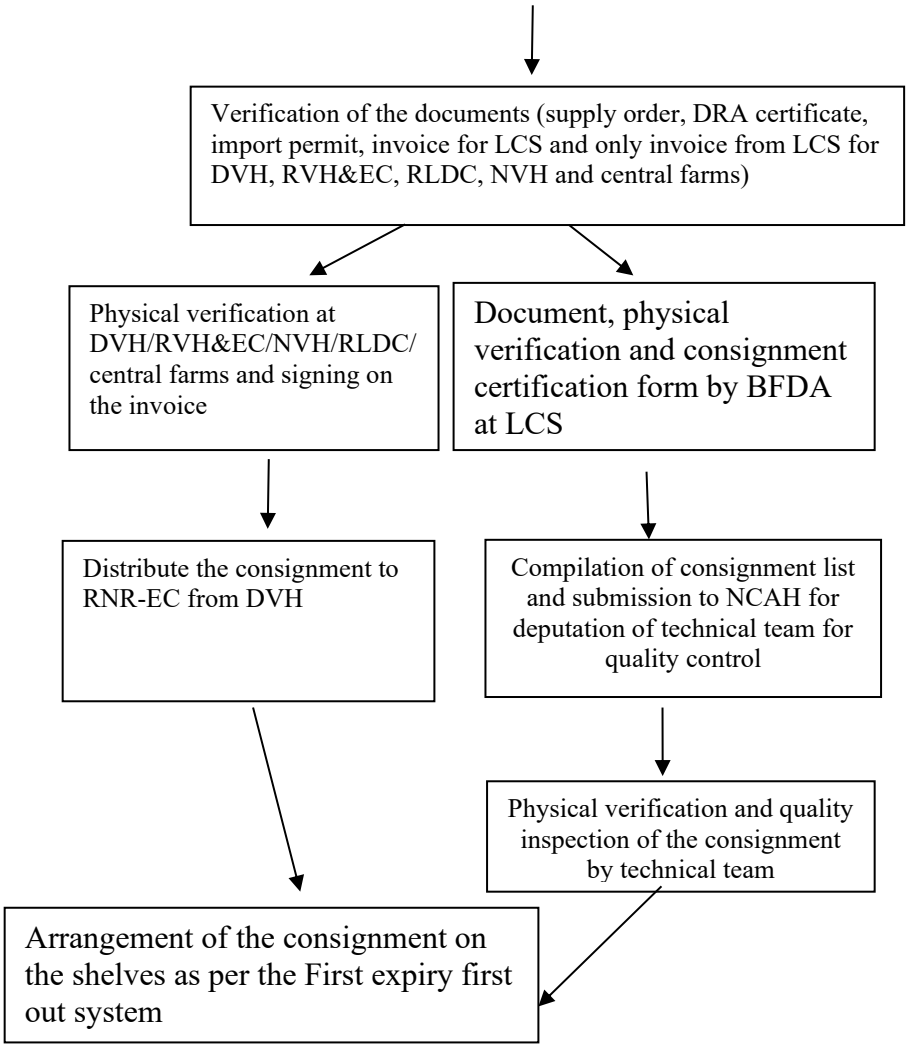
4.2 Scope
This SOP is applicable to agencies involved when receiving the consignment.

4.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1.	Store Officer, LCS	• Receive the consignment from the suppliers • Process for verification and inspection • Process bills for settlement after verification • Store appropriately
2.	Veterinarians, Para-Veterinarians of NVH/RLDC/RVH & EC/LEC/Central farms	• Receive the consignment from LCS • Verify the stock and challans • Store accordingly

4.4 Process Map in Flow Chart

Receive the consignment



4.5 Procedure

4.5.1 Receive the consignment from the source

4.5.2 Verification of the Company invoice, supply order, import permit, and DRA certificate at LCS and invoice at NVH/DVH/RLDC/RVH&EC

4.5.3 Verify the documents and the consignments and certify the consignment by BFDA at LCS and physical verification of the consignment at NVH/DVH/RLDC/RVH&EC and central farms.

4.5.4 Compilation of the consignment list and submit to NCAH for Quality control at LCS.

4.5.5 Physical, document verification and quality inspection by the technical team at LCS.

4.5.6 At DVH level the consignment will be further distributed to RNR-EC.

4.5.7 Arrangement of the consignment on the shelves according to the label and first expiry first out system

4.6 References

- SOP on SOP format – Drug Regulatory Authority, Thimphu. Good Pharmacy Practice (GPP) in Developing Countries: Recommendations for Stepwise Implementation

5. SOP for Storage and Management of Medicine, Non-drug items and Equipment for LCS

5.1 Purpose

This SOP describes the procedures for storage and management of veterinary medicines, non-drug items and equipment for Livestock Central Store (LCS).

5.2 Scope

This SOP is applicable to receiving goods, storage, management and dispatching of goods.

5.3 Responsibilities

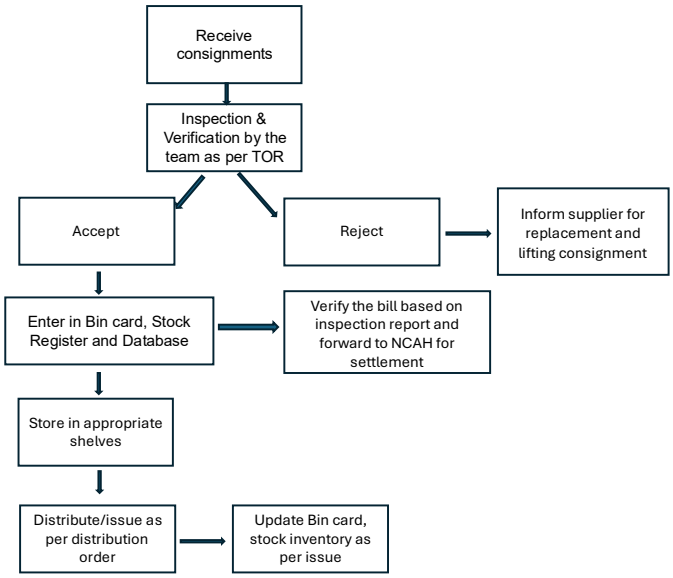
All the staffs of LCS should follow this SOP

Sl. No.	Official Designation	Responsibilities
1.	Store Officer	• Planning, budgeting and management of LCS. • Supervise receiving of goods, inspection and verification, labeling, storage, dispensing, recording & updating in the register & database, preparing reports & forwarding to NCAH. • Facilitate submission of write-off proposal of the • expired medicines and disposal of expired medicines. Verify and submit bills/ invoice to NCAH.

2	Assistant store Officer/ para-veterinarian	• Receive goods, inspect, verify and storage of goods. Labelling of storerooms and shelves, storage, recording of temperature of rooms and refrigerator. • Update bin card, stock register and issue goods received note and certify invoice received from the suppliers. • Distribution of medicines and non-drug items based on distribution order received from NCAH following the principle of first-in/first-out (FIFO) or first-expiry/first-out (FEFO).
2.	Store Assistant	• Supervise in maintaining cleanliness of store.
		• Assist Assistant Store Officer in receiving of goods, inspection, storage, update bin card and stock entry, and preparation of goods received note. • Packing of medicines and non-drug items, labeling of packages and supervise loading of the goods at the time distribution to field. • Maintain temperature-recording sheets of storerooms and refrigerators.
3.	Administrative Assistant	• Assist Store Officer in Administrative works including maintaining of files. • Update EVDP database on regular basis. Reconciliation of physical balance, stock register and database. • Assist Store Officer in facilitation of obtaining write off approval for expired medicines. • Generate Goods issue note/ invoice at the time of distribution to the field.
4.	Account Assistant	• Annual budget preparation, financial management and submission of financial reports. • Maintenance of personal files and general correspondences. • Assist Store Officer and Assistant Store Officer in compilation and submission of nearing drug expiry, internal drug mobilization and for obtaining write-off approval for the expired medicines. • Assist Store Officer in preparation and submission of drug reports.
5.	Store Attendant/ daily	• Unloading and arrangement of consignments in

	wage workers	the store as per SOP. • Maintenance of cleanliness of the storerooms, shelves and LCS premises. • Packaging and loading of consignments at the time of distribution. • Assist Assistant Store Officer and Store Assistant during physical inspection, verification, segregating of expired and non-expired drugs and during the disposal of hazardous and non-hazardous drugs etc. Any tasks assigned by Store Officer and Assistant • Officer.

5.2 Process Map in Flow Chart



5.3 Procedure

5.1 Receive the goods from the suppliers along with documents (invoice, DRA certificates/ valid import authorization).

5.2 Isolate the goods until DRA inspection and quality inspection by verification team are completed.

5.3 Check the document for all formalities like DRA certificates/import authorization, challan, invoice, supply order, transportation documents, etc.

5.4 Complete the formalities of receiving the goods from supplier/driver and duly sign the number of packages and quantity of items received.

5.5 Inspection

5.4.1 Inspect the drugs, non-drug items and equipment received as per the inspection terms of reference.

5.4.2 For quality inspection in LCS, related samples retained in RVH & EC, Phuntsholing should be formally acquired and referred for inspection. Once the inspection is completed, the samples should be again handed over to RVH & EC), Phuntsholing immediately. Samples shall be allowed to go out of RVH & EC, Phuntsholing only on authorization from NCAH.

5.6 Discrepancies, variations and damage are noted on the invoice as well as inspection report.

5.7 Verify the invoice, DRA import authorization, supply order, item code, brand names and other relevant documents.

5.8 Goods received by LCS should have a minimum of 18 months expiry period unless justified by the principal manufacturing companies and accepted by NCAH.

5.9 If the goods are accepted,

5.9.1 Storeroom

5.9.1.1 The facility should have a separate storeroom for quarantining of goods and medicine and non-drug items storage with all rooms properly labelled

5.9.1.2 It should be well ventilated and protected from direct sunlight.

5.9.1.3 It should have adequate medicine racks with proper labels and well designated for storing medicines, non-drug items and veterinary equipment.

5.9.1.4 All rooms should have room thermometer with temperature monitoring chart maintained for each room, which should be recorded twice a day (morning and evening).

5.4.3 Management of store

5.4.3.1 All persons working in store should wear proper working dress with nametag.

5.4.3.2 Enter the quantity received in bin card/ stock register/ database.

5.4.3.3 Record batch number, manufacture date and expiry date in stock register/ database.

5.4.3.4 Transfer the accepted goods to their allocated storage positions in the store where they are stored in first-expiry/first-out (FEFO) and or first- in/first-out (FIFO)

5.4.3.5 The medicine racks should be labeled in alphabetical orders and accordingly arranged in the racks.

5.4.3.6 Prepare receiving reports and forward the challan/ letter of acknowledgement to NCAH.

5.4.3.7 The medicine racks should have bin cards hung as per therapeutic groups and in the alphabetical orders within the same group. Each receive and issue of goods should be duly recorded on the bin card.

5.4.3.8 The controlled drugs like Ketamine and Diazepam should be stored in medicine

storage shelf (steel almirah) and kept under lock and key. The Store Officer should strictly monitor the issue and usage.

5.4.3.9 Those drugs requiring to be kept in cold condition should be stored in refrigerator at the required temperature. The temperature recording chart for each refrigerators should be maintained and recorded at least twice a day (morning and evening).

5.4.4 Management of nearing expiry drugs

5.4.4.1 Maintain record of nearing expiry drugs, which are within six months of expiry period.

5.4.4.2 Communicate with NCAH for internal mobilization of nearing expiry drugs. NCAH in turn should liaise with regional EVDP focal points and LCS for internal mobilization of nearing expiry drugs.

5.4.4.3 Distribute nearing drugs expiry from LCS based on distribution order from NCAH.

5.4.5 Management of expired drugs.

5.4.5.1 Segregate the expired drugs.

5.4.5.2 Pack them in a container and store them in a separate area.

5.4.5.3 Maintain a record of expired drugs.

5.4.5.4 Prepare write off from Dzongkhag/DoL/MoAL as per existing financial rules and regulations (on quarterly basis).

5.4.5.5 Submit the list of expired drugs to NCAH, Serbithang for facilitation of disposal after acquiring write-off approval.

5.4.5.6 Segregate expired drugs as per pharmaceutical waste management guidelines developed by DRA.

5.4.5.7 All the expired medicines should be transported to LCS after completion of all formalities which in turn will be lifted by the suppliers.

5.4.6 If the goods are rejected:

5.4.6.1 Rejected goods should be given full justifications for rejection by Inspection/ Verification team.

5.4.6.2 Return the rejected goods to the suppliers by LCS with copy of surrendered list and justification to NCAH

5.4.7 Dispense/Dispatch

5.4.7.1 Issue of goods should be strictly based as per distribution order received from NCAH. Distribution order prepared by NCAH should be strictly as per the annual indents submitted by respective units/ Dzongkhags.

5.4.7.2 For emergency or ad hoc requirements, NCAH shall procure an additional 10% of the requirements and keep in LCS stock readily available to meet emergency/ ad hoc needs.

5.4.7.3 Goods to be issued should have adequate expiry period and goods issued should never be of less than 6 months expiry period.

5.4.7. 4 Goods which are of less than 6 months expiry period should be proposed for immediate internal mobilization

5.4.7.5 Issue the goods and record in bin card, stock register and database.

5.4.8 Update the stock register/ database on real time basis. Reconciliation of physical stock, bin card, stock register and database should be done on weekly basis.

5.5 Related Forms or Work Instructions

5.5.1 SOP on Disposal of Pharmaceutical and Biological Wastes

5.5.2 http://dra.gov.bt/wp-content/uploads/2015/07/Guideline-for-disposal-of-Pharmaceutical-Waste.pdf.

5.6 References

5.6.1 Standard Operating Procedure for certificates of medicinal products, Europe.
5.6.2 Management Sciences for Health 2012 – Medical stores Management.
5.6.3 Pharmaceutical waste management guideline by DRA.

6. SOP for Mass Distribution of Medicines, Vaccines, Consumables & Equipment

6.1 Purpose

This SOP describes the steps for annual distribution of veterinary medicines, equipment, and consumables.

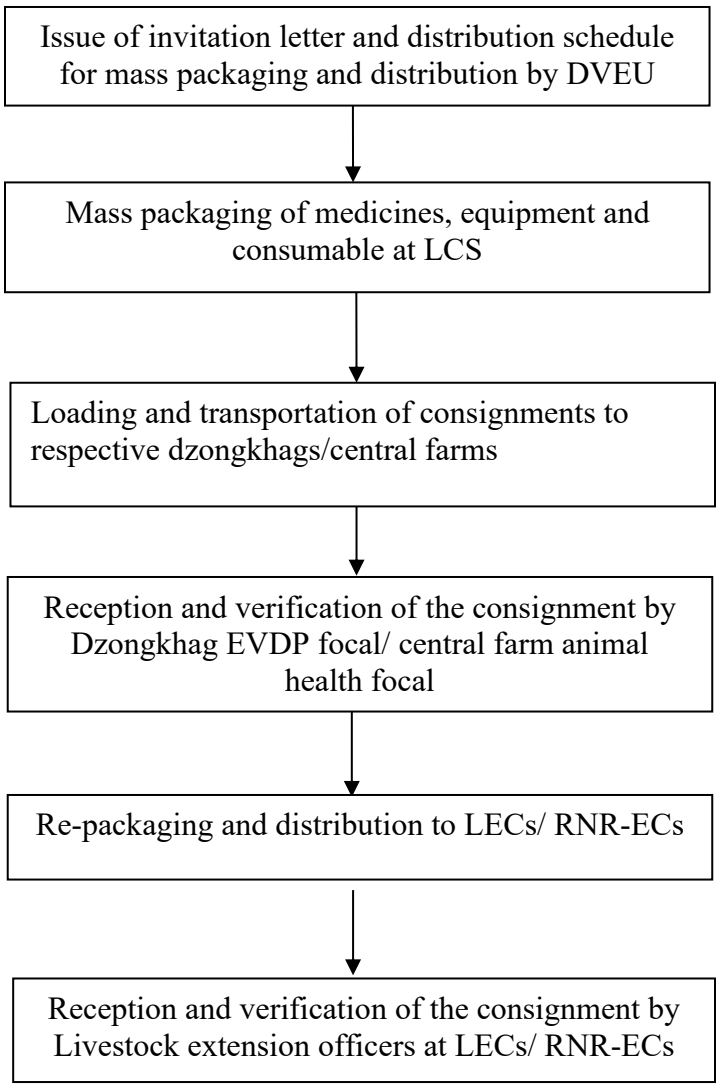
6.2 Scope

This SOP is applicable to the institutions involved in distribution of veterinary medicines, equipment, and consumables.

6.3 Responsibilities

Sl.no	Official Designation	Responsibilities
1	DVEU	1. Prepare mass distribution schedule 2. Send invitation to EVDP focal in DVHs/ Central farms/ agencies for mass packaging and distribution of consignment
2	Regional EVDP focal person	1. To coordinate and monitor during the packaging and distribution of medicines, equipment, and consumables as per the distribution list.
3	Dzongkhag EVDP focal person	1. To verify and monitor the packaging of medicines, equipment, and consumables as per the distribution list at LCS. 2. To receive and verify consignment at DVH. 3. To pack and redistribute to LECs/RNR-ECs
4	Central Farms/agencies	1. To verify and monitor the packaging of medicines, equipment, and consumables as per the distribution list at LCS.
5.	Livestock Central, Store In charge	1. Overall coordination of mass packaging and distribution of the consignment 2. Logistic arrangement (working lunch) during mass packaging and distributions. 3. Preparing In-voice

6.4 Process Flow



6.5 Procedure

6.5.1 The DVEU will prepare annual distribution schedule and send invitation letter to respective EVDP focal person at Dzongkhag/ central farms/ agencies

6.5.2 As per the distribution schedule and invitation letter, the respective EVDP focal persons will go to LCS

6.5.3 Verification and packaging at LCS

6.5.3.1 DVEU (NCAH) and Regional EVDP focal person and will verify the medicines, equipment and consumables as per the distribution list
6.5.3.2 The respective Dzongkhag/ Central farm EVDP focal persons will monitor the packaging of the verified medicines, equipment and consumables.
6.5.4 Loading and Transportation
6.5.4.1 The Central store officer will prepare the transportation schedule and inform respective dzongkhags/agencies
6.5.4.2 The central store officer will dispatch the consignment as per the schedule along with invoice.
6.5.5 Reception of consignment
6.5.5.1 The EVDP focal person at Dzongkhag/ central farms receive and verify the consignment.
6.5.5.2 The EVDP focal person at Dzongkhag/ central farms will send a copy of signed invoice to LCS after the verification of the consignment.
6.5.6 The EVDP focal person at Dzongkhag will repack and dispatch the medicines, equipment and consumables as per the indent by the LECs/RNR-ECs
6.5.7 The staff at LECs/RNR-ECs will receive the consignment and enter in the stock register.

6.6 Related Forms or Work Instructions
6.6.1 SOP for Consignment Receipt
6.6.2 SOP for handling drug in store

6.7 References
6.7.1 SOP on SOP format – Drug Regulatory Authority, Thimphu.

7. SOP for Storage and Management of Medicine, Vaccine, Non-drug items and Equipment for VHs & LECs

7.1 Purpose
This SOP describes the procedures for storage and management of veterinary medicines, vaccines non- drug items and equipment for NVH, RLDC /RVH & EC, DVHs and LECs.

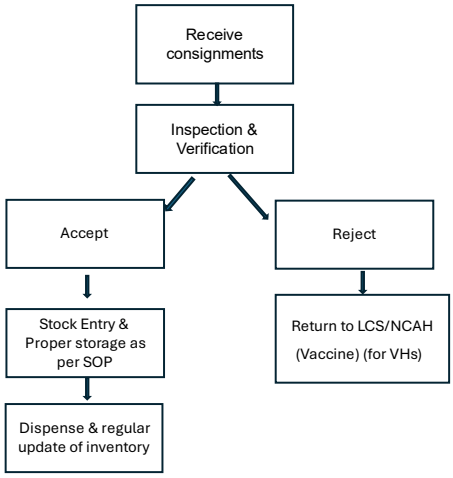
7.2 Scope
This SOP covers the procedures for receiving, storage, management and dispatching of goods.

7.3 Responsibilities

All the staffs of NVH/RLDC RVH & EC, /DVHs/LECs should follow this SOP.

Sl. No.	Official Designation	Responsibilities
1.	Veterinary Officer	1. Dzongkhag EVDP focal person. 2. Scrutinize annual indents and submit to regional/national focal points and NCAH. 3. Supervise receiving of goods, inspect and verification, labeling, storage, dispensing, recording & updating in the register & database, preparing reports & forwarding to NCAH. 4. Oversee distribution to Geog centers as per indent. 5. Manage nearing expiry and expired medicines. 6. Arrange emergency/adhoc requisition.
2.	Veterinary Paraprofessionals	1. Prepare indent and submit to VOs/In-Charge 2. Receiving of goods, inspect and verification, labeling, storage, dispensing, recording & updating in the register & database, preparing reports & forwarding to Regional focal point/NCAH. 3. Record storeroom and refrigerator temperature twice in day (morning & evening).
3.	Geog staff	1. Prepare indent and submit to VOs/In-Charge 2. Receive goods, inspect and verification, labeling, storage, dispensing, recording & updating in the register & database, preparing reports & forwarding to DLOs. 3. Manage nearing and expired medicines. 4. Record storeroom and refrigerator temperature twice in day (morning & evening). 5. Submit emergency/ad hoc requisition to VHs/DVH

7.4 Process Map in Flow Chart



7.5 Procedure

7.5.1 Receive the goods from LCS/NCAH (vaccine) (for NVH/RVH / DVH (for LECs).
7.5.2 Check the documents.
7.5.3 Inspection
7.5.3.1 Inspect the medicine/non-medicines are as per the indent, has enough shelf life for medicines and with no damages at the time of receiving.
7.5.3.2 Discrepancies, variations and damage are noted on the invoice.
7.5.3.3 Verify the invoice.
7.5.3.4 Prepare receiving reports and forward the challan/ letter of acknowledgement to DVH/RLDC/NCAH.
7.5.4 Storage & management of drug and non-drug items:
7.5.4.1 Storeroom

- It should be well ventilated and protected from direct sunlight.
- It should have adequate medicine racks with proper labels and well designated for storing medicines, non-drug items and veterinary equipment.
- All rooms should have room thermometer with temperature monitoring chart maintained for each room, which should be recorded twice a day (morning and evening).

7.5.4.2 Store management

- All persons working in store should wear proper working dress with nametag.
- Enter the quantity received in stock register/ database.
- Record batch number; manufacture date and expiry date in stock register/ database.
- Transfer the accepted goods to their allocated storage positions in the store where they are stored in first expiry/first-out (FEFO) and or first- in/first-out (FIFO).
- The medicine racks should be labeled in alphabetical orders and accordingly arranged in the racks.
- The controlled drugs like Ketamine and Diazepam should be stored in medicine storage shelf (steel almirah) and kept under lock and key. The In-charge should strictly monitor the issue and usage.
- Those drugs requiring to be kept in cold condition should be stored in refrigerator at the required temperature. The temperature recording chart for each refrigerators should be maintained and recorded at least twice a day (morning and evening).

7.5.4.3 Management of nearing expiry drug

- Maintain record of nearing expiry drugs, which are within three months of expiry period.
- Communicate with Dzongkhag/Regional/National EVDP focal points for internal mobilization of nearing expiry drugs.
- Arrange transport of nearing expiry drugs for immediate utilization.

7.5.4.4 Management of expired drugs

- For expired drugs, segregate the expired drugs.
- Pack them in a container and store them in a separate area.
- Maintain a record of expired drugs.
- Prepare write off from DoL/MoAF/Dzongkhag Administration as per existing financial rules and regulations on half yearly basis.
- Submit the list of expired drugs to DVH (for LECS) and NCAH (for VHs) for facilitation of disposal.
- Segregate expired drugs as per pharmaceutical waste management guidelines developed by DRA.
- All non-hazardous pharmaceutical wastes should be disposed at the LECs/VHs/Farms itself.
- All hazardous pharmaceutical wastes should be transported to LCS after completion of all formalities.

7.5.4.5 If the goods are rejected:

- Keep all the rejected goods in a separate room (if space is available) and do not mix the rejected goods with the accepted goods.
- Provide justification and prepare a list of rejected goods along with their reasons for rejection against each item.
- Return the rejected goods with the list to DVH (for LECs) and LCS (VHs). Submit a copy to NCAH.

7.5.4.6 Dispense/Dispatch

- Receive requisition from within the hospital or LECs in that Dzongkhag.

- Issue the goods.
- Enter in the stock register.
- Update the stock register and database weekly.

7.6 Related Forms or Work Instructions

7.6.1 SOP on Disposal of Pharmaceutical and Biological Wastes

7.6.2 http://dra.gov.bt/wp-content/uploads/2015/07/Guideline-for-disposal-of-Pharmaceutical-Waste.pdf.

7.7 References

7.7.1 Standard Operating Procedure for certificates of medicinal products, Europe.

7.7.2 Management Sciences for Health 2012 – Medical stores Management.

7.7.3 Pharmaceutical waste management guideline by DRA.

8. SOP for Emergency Supply management

8.1 Purpose

This SOP describes the procedure for emergency requisition for medicine/equipment

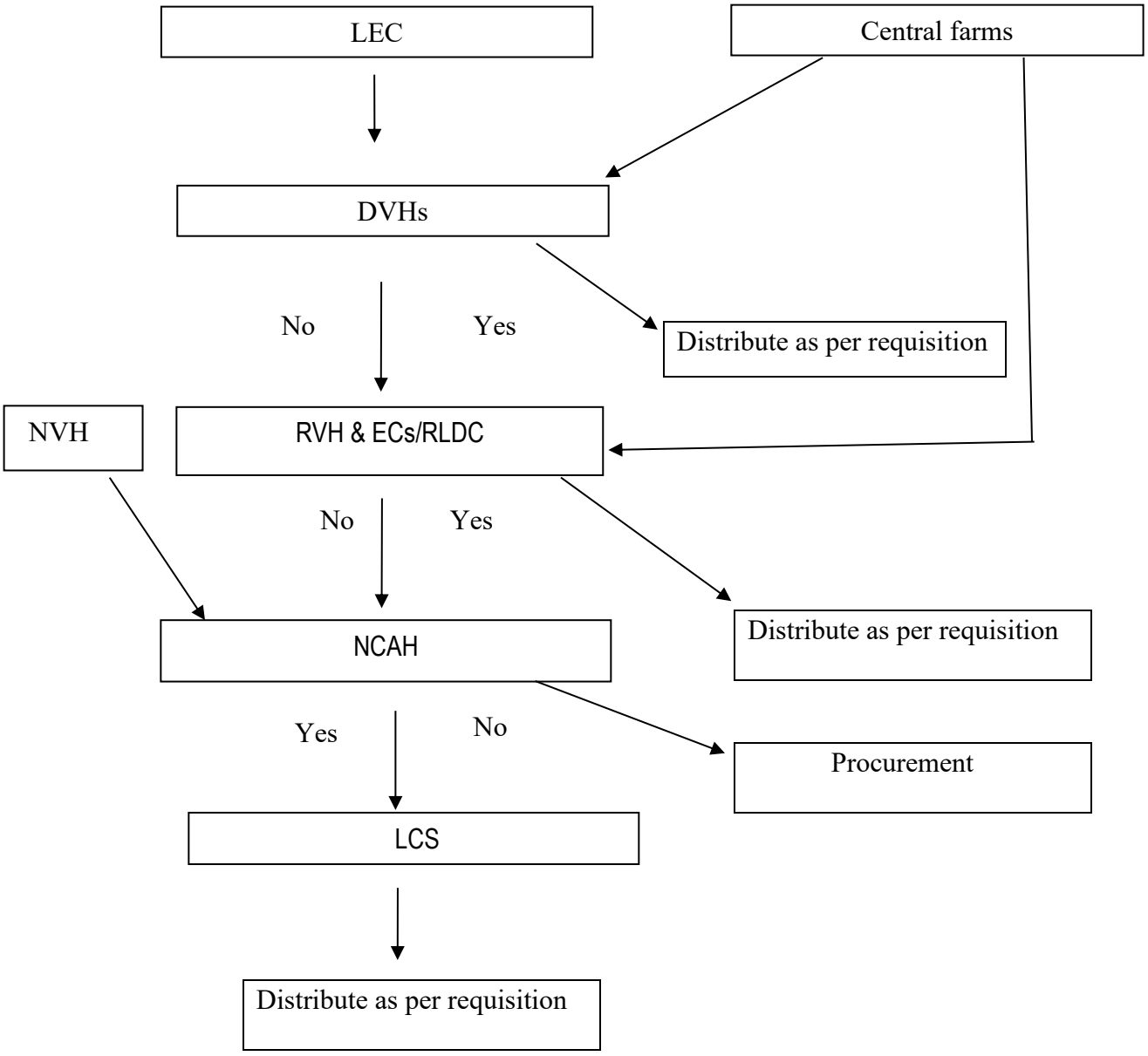
8.2 Scope

This SOP is applicable for NCAH/NVH/RVH & ECs/DVH/Farms/RNR-ECs.

8.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1	Veterinarians/ Veterinary Para-Professional/Store in-charges	Requisition for emergency medicines/equipment/Vaccines

8.4 Process Map in Flow chart



7.6 Procedure

7.6.1 Receive and validate the requirement of emergency requisition
7.6.2 Receive the requisition and confirm the details of the centers along with quantity
7.6.3 Understand and verify the requisition.

7.6.4 Go through the list of the requisition
7.6.5 Confirm that the quantity requested and check for stock balance.
7.6.6 Prepare and label items for issue.
7.6.7 Select the item by reading the label and cross matching the product name and strength against the requisition.
7.6.8 Check the stock to make sure that it has not expired and choose the oldest stock (First-in/ First-out or First expiry/ First out).
7.6.9 Arrange the required quantity with proper packaging.
7.6.10 Prepare the invoice and other necessary documents
7.6.11 Arrange proper mode of transportation. If required items is not available at the level, forward further along with proper documentation
7.6.12 Make a final check.
7.6.13 Keep necessary record in the stock registers and updates to other online

8.6 Related Forms or Work Instructions
8.6.1 SOP for annual indent.

8.7 References
8.7.1 SOP on SOP format – Drug Regulatory Authority, Thimphu.
8.7.2 Management Sciences for Health 2012 – Medical stores Management. Good Pharmacy
8.7.3 Practice (GPP) in Developing Countries: Recommendations for Stepwise Implementation.

9. SOP on Bill settlement for Veterinary Medicine, non-medicine items and Equipment

9.1 Purpose
This SOP describes the procedure for timely settlement of bill(s) for Veterinary medicines, non-medicine items and equipment received by LCS, Phuntsholing

9.2 Scope
This SOP is applicable for Livestock Centre Store (LCS, Phuntsholing) & NCAH, Serbithang

9.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1	Store Officer, LCS, Phuntsholing	Verification, stock entry and Submission of bills
2	Head, DVEU	Verifies the bill & submits

3	Program Director, NCAH, Serbithang	Cross checking and Submission of bills to Cluster Finance Services, MoAL
4	CFS, MoAL, Thimphu	Verification and payment of bill to the Supplier

9.4 Process Map in Flow Chart

Livestock Centre Store (LCS) receives the consignments

↓

LCS request Bhutan Food & Drug Authority for physical verification& inspection of medicines

↓

BFDA performs physical verification & inspection of medicine

↓

LCS request DVEU for physical verification & inspection team formation

↓

The Team carry out physical verification & inspection

↓

Store Assitant carry out stock entry as per physical verification & inspection report

↓

Store officer carry out Verification and submission of bills to NCAH

↓

Cross-verification of bills by NCAH

↓

NCAH submit the bills to cluster finance for making payment

7.7 Procedure

7.7.1 LCS receives the consignment along with the bill from the Supplier(s).
7.7.2 LCS performs physical verification of the items received.
7.7.3 LCS carry out stock entry as per the physical verification and inspection report.
7.7.4 LCS works on penalty for liquidity damage.
7.7.5 LCS forward the bill to NCAH within one week after receiving the consignment.
7.7.6 NCAH, Serbithang cross checks and submits verified bills within one week to CFS, MoAL for necessary payment.
7.7.7 CFS, MoAL makes necessary payment within one week after receiving the verified bills.

9.6 Related Forms or Work Instructions

NA

9.7 References

9.7.1 SOP on SOP format – Drug Regulatory Authority, Thimphu

10. SOP for Usage, Distribution, Transportation, Storage, and Disposal of Controlled Drugs in Animal Health Centres and Veterinary Hospitals

10.1 Purpose

This SOP outlines the procedures for the safe, effective, and accountable management of controlled drugs in Animal Health facilities in Bhutan. For **Public safety (**Preventing the diversion and misuse of controlled drugs) and **Animal welfare (**Ensuring the appropriate and ethical use of controlled drugs in animal treatment).

10.2 Scope

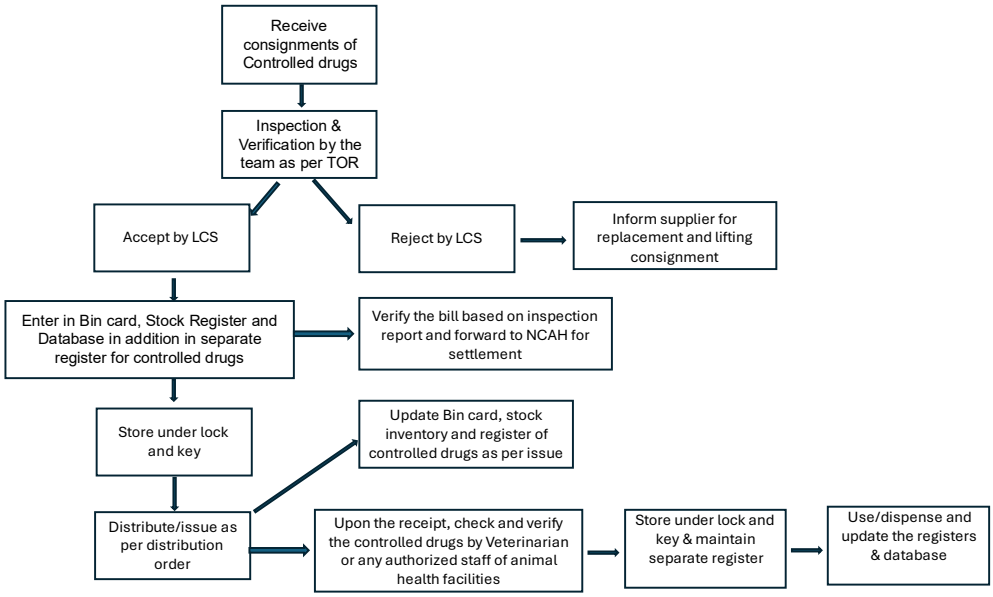
This SOP applies to all the Animal Health facilities in Bhutan that handle controlled drugs. It covers all aspects of controlled drug management.

10.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1	Veterinary Officer/ In-Charge:	1 Overall responsibility for the safe and secure management of controlled drugs in the facility. 2 Ensure compliance with this SOP and all relevant regulations. 3 Conduct regular audits of controlled drug stocks.

2	Authorized Personnel	1 Responsible for the proper prescription, administration, and record-keeping of controlled drugs. 2 Ensure accurate and timely recording of all controlled drug transactions.
3	All Staff	1 Comply with all security measures and reporting requirements. 2 Report any suspected misuse or diversion of controlled drugs.

10.4 Process flow chart



10.5 Procedures

10.5.1 Procurement and Receipt

- Controlled drugs shall be procured only from authorized sources with valid licenses issued by Bhutan Food and Drug Authority.
- All shipments of controlled drugs must be accompanied by a valid invoice and a copy of the import/purchase permit.
- Upon receipt, the Veterinary Officer-in-Charge or a designated representative shall:
  - ✓ Verify the quantity and authenticity of the drugs.
  - ✓ Inspect the packaging for any signs of tampering.
  - ✓ Record the receipt in the Controlled Drug Register.

10.5.2 Storage and Security

- Controlled drugs shall be stored in a secure, locked room or cabinet with a double lock system.
- The storage area must be well-ventilated, dry, and protected from extreme temperatures and humidity.
- Access to the storage area shall be restricted to authorized personnel.
- A regular inventory of controlled drugs shall be conducted and documented.

10.5.3 Usage and Dispensing

- Controlled drugs shall only be used for legitimate veterinary purposes and as per prescription.
- Prescriptions for controlled drugs must be written in clear, legible handwriting and include the following information:
  - ✓ Animal species
  - ✓ Diagnosis
  - ✓ Drug name and dosage
  - ✓ Quantity prescribed
  - ✓ Date of prescription
  - ✓ Veterinarian's signature (and registration number)
- Controlled drugs shall be dispensed only to authorized personnel or directly to the animal under the supervision of an authorized veterinarian.
- All controlled drug transactions must be recorded in the Controlled Drug Register.

10.5.4 Transportation

- Controlled drugs shall be transported in secure, tamper-proof containers.
- During transportation, the drugs shall be accompanied by a valid transportation permit and a manifest listing the quantity and type of drugs (see annexure I)

- Transportation shall be carried out by authorized personnel or through secure courier services.

10.5.5 Record-Keeping

- Maintain a detailed Controlled Drug Register, including (see annexure II):
  - ✓ Date of receipt
  - ✓ Name, dosage form, presentation and quantity of drugs received
  - ✓ Date of Manufacture
  - ✓ Date of expiry
  - ✓ Batch number
  - ✓ Supplier information
  - ✓ Date of dispensing/issuing
  - ✓ Quantity dispensed/issued
  - ✓ Recipient information
  - ✓ Prescribing veterinarian's information
  - ✓ Date of destruction (if applicable)
  - ✓ Signatures of authorized personnel

10.5.6 Disposal

- Controlled drugs that are expired, damaged, or no longer required shall be disposed of in a safe and environmentally sound manner.
- Disposal shall be carried out under the supervision of the Veterinary Officer-in-Charge or a designated official.
- A record of all drug disposals shall be maintained.

10.5.7 Monitoring and Review

- The Veterinary Officer-in-Charge shall conduct regular audits of controlled drug stocks and records.
- The SOP shall be reviewed and updated periodically to ensure its effectiveness and compliance with current regulations.

10.5.8 Violations and Sanctions

Any violation of this SOP will be subject to disciplinary action, including but not limited to:

- Suspension of veterinary license
- Fines
- Legal action

10.5.9 Training

All personnel involved in the handling of controlled drugs shall receive adequate training on this SOP and relevant regulations.

10.5.10 Emergency Procedures
In case of any theft, loss, or suspected diversion of controlled drugs, the Veterinary Officer-in-Charge shall immediately notify the relevant authorities, including the Bhutan Food and Drug Authority (BFDA) and the police.

10.5.11 List of controlled drugs in EDVL:

a. Sedatives/Tranquilizer
Ketamine inj.
b. Non-patent/chemical drugs
Potassium permanganate (crystal)

c. Anti-convulsant drugs
Diazepam inj
Phenobarbitone sodium inj.
d. Analgesics
Tramadol inj
e. Wildlife (specific)
Etorphine hydrochloride

10.6 Related Forms or Work instructions
NA

10.7 References:

NA

11. SOP for Veterinary Pharmacovigilance

11.1 Purpose:

This SOP outlines the procedures for veterinary pharmacovigilance, ensuring the safety and efficacy of veterinary medicinal products used in the country. It aims to establish a system for the detection, reporting, assessment, and prevention of adverse events associated with these products.

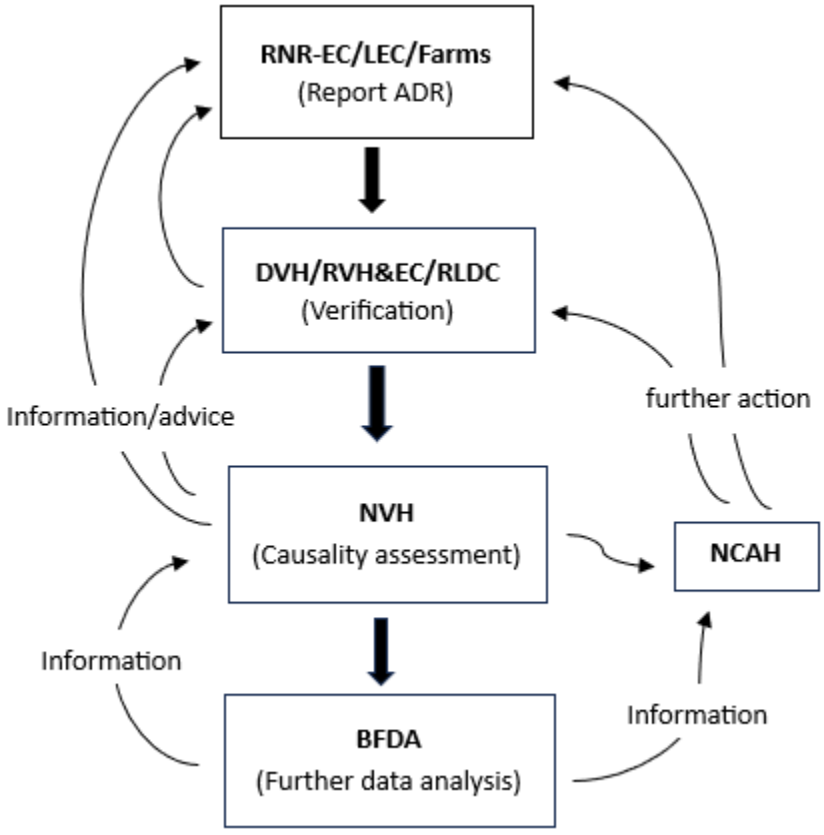
11.2 Scope

This SOP applies to all stakeholders involved in the use, distribution, and regulation of veterinary medicinal products in Bhutan, including:

11.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1	Veterinary Officer/ In-Charge:	1 Responsible for detecting and reporting suspected adverse events in animals under their care.
2	Animal Owners/Keepers	1 Responsible for observing their animals for any unusual reactions and reporting them.
3	Pharmaceutical Companies	1 Responsible for reporting adverse events associated with their products.
4	NVH	1 Responsible for receiving, assessing, and managing adverse event reports, conducting signal detection, and implementing risk management measures.

11.4 Procedures flow:



11.5 Procedures

11.5.1 Adverse Event Detection and Reporting:

- **Who to Report:** Any suspected adverse event should be reported.
- **How to Report:** Use the official Veterinary Pharmacovigilance Reporting Form. This form can be obtained from the NVH website.
- **When to Report:** Report suspected adverse events as soon as possible, especially serious adverse events.
- **Where to Report:** Submit the completed reporting form to: Designated Pharmacovigilance Contact Person/Unit reflected in the flow chart. (Annexure 1)

11.5.2 Case Management:

- **Receipt of Reports:** The designated pharmacovigilance unit will receive and log all reports of suspected adverse events.
- **Data Entry:** Information from the reporting forms will be entered into a pharmacovigilance database.
- **Case Assessment:** Trained personnel will assess each case, including:

  - ✓ Reviewing the reported event details
  - ✓ Evaluating the animal's medical history
  - ✓ Assessing the product used (name, batch number, route of administration, etc.)
  - ✓ Determining the causality (likelihood of the product causing the reaction)
  - ✓ Classifying the event's seriousness.

11.5.3 Signal Detection and Analysis:

- The pharmacovigilance unit will regularly analyse the data in the database to identify potential safety signals.
- Signal detection will involve:

  - ✓ Monitoring the frequency and patterns of reported adverse events.
  - ✓ Comparing observed events with expected events (based on product information).
  - ✓ Investigating clusters of similar events.

11.5.4 Risk Management and Communication:

- If a safety signal is identified and confirmed, risk management measures will be implemented. These may include:

  - ✓ Product label changes
  - ✓ Restrictions on product use
  - ✓ Withdrawal of the product from the market
  - ✓ Public warnings/alerts

- Communication of safety information will be disseminated to:

  - ✓ Veterinarians
  - ✓ Animal owners/keepers
  - ✓ Pharmaceutical companies
  - ✓ The public

11.5.5 Follow-up:

- Follow-up investigations may be conducted for specific cases to gather additional information.
- Reporters may be contacted for clarification or further details.

11.5.6 Training:

Regular training will be provided to all stakeholders on veterinary pharmacovigilance procedures, including adverse event detection, reporting, and case management.

11.5.7 Quality Assurance:

The pharmacovigilance system will be regularly audited to ensure its effectiveness and compliance with this SOP.

11.5.8 Review and Revision:

This SOP will be reviewed and revised periodically or as needed to reflect new information and best practices.

11.6 Related Forms or Work instructions

NA

11.7 References:

12. SOP for Disposal of Veterinary Medicinal and Pharmaceutical Waste

12.1 Purpose

This SOP outlines the procedures for the safe and environmentally sound disposal of veterinary medical and pharmaceutical waste (VMPW) generated by Animal Health facilities.

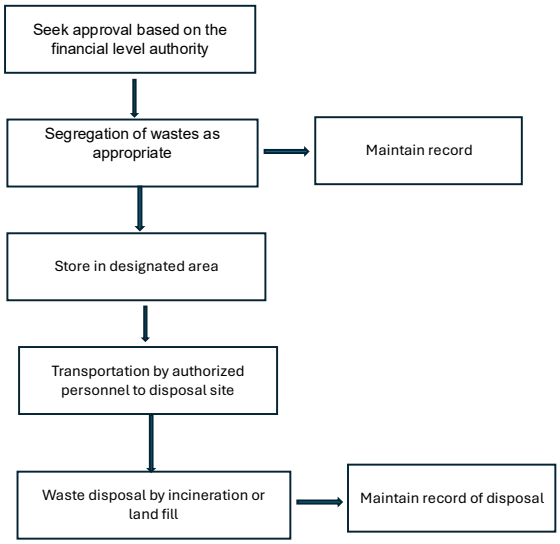
12.2 Scope

This SOP applies to all Animal Health facilities in Bhutan that generate VMPW.

12.3 Responsibilities

Sl. No.	Official Designation	Responsibilities
1	Veterinary Officer/ In-Charge:	1. Overall responsibility for the safe and environmentally sound disposal of VMPW. 2. Ensure compliance with this SOP and all relevant regulations. 3. Conduct regular inspections of waste disposal areas.
2	All staff	1. Segregate waste according to its type. 2. Place waste in appropriate containers. 3. Handle and dispose of waste with care to minimize risks. 4. Report any incidents related to waste disposal.

12.4 Process Flow chart



12.5 Procedure

12.5.1 Waste Segregation

- **Sharps:** Place in puncture-resistant containers labeled "Sharps." (**Yellow puncture-proof containers**)
- **Infectious Waste:** Place in leak-proof bags or containers labeled "Infectious Waste." (**Yellow bags or bins**)
- **Pharmaceutical Waste:** Place in leak-proof containers labeled "Pharmaceutical Waste." (**Blue Bins**)
- **Chemical Waste:** Place in leak-proof containers labeled with the specific chemical name. (**Purple containers**)
- **General Waste:** Place in appropriate containers for general waste disposal. (**Black bags**)

12.5.2 Waste Storage

- All waste containers shall be stored in a secure, designated area, away from food and water sources.
- Storage areas shall be well-ventilated and protected from extreme temperatures and humidity.
- Containers shall be clearly labeled with the type of waste and the date of collection.

12.5.3 Waste Transportation

- VMPW shall be transported to designated disposal sites by authorized personnel or licensed waste management companies.
- Transportation vehicles shall be properly maintained and equipped with appropriate safety gear.
- All transportation shall be conducted in accordance with local regulations and guidelines.

12.5.4 Waste Disposal

- **Sharps:** Incineration or autoclaving followed by secure disposal.
- **Infectious Waste:** Incineration or autoclaving.
- **Pharmaceutical Waste:** Incineration or disposal at designated hazardous waste facilities.
- **Chemical Waste:** Disposal at designated hazardous waste facilities.
- **General Waste:** Disposal at designated landfills or through other appropriate methods.

12.5.5 Record-Keeping

- Maintain detailed records of all VMPW generated and disposed of.
- Records shall include the type and quantity of waste, date of disposal, and the name of the disposal agency. (refer waste generation record of MPD, BFDA)

12.5.6 Training

- All staff shall receive training on the proper handling, storage, and disposal of VMPW.
- Training shall cover relevant safety procedures, environmental regulations, and emergency response protocols.

12.5.7 Emergency Procedures

- In case of any accidental spills or releases of VMPW, immediately implement emergency procedures.
- Notify the appropriate authorities, such as the Department of Environment and the National Environment Commission.
- Take necessary steps to contain the spill and minimize its impact on the environment.

12.5.8 Monitoring and Review

- Regularly monitor and evaluate the effectiveness of the waste disposal system.
- Review and update this SOP periodically to ensure compliance with current regulations and best practices.

12.5.9 Compliance with Regulations

This SOP shall be implemented in accordance with all relevant national and international environmental regulations, including the Environmental Rules and Regulations of Bhutan.

12.5.10 Review and Amendments

- This SOP must be reviewed annually and updated as needed to ensure continued compliance with waste disposal regulations.
-

12.6 Related Forms or Work instructions

-

12.7 References:

Annexure I : Control Drugs Shipment Form

Ref No: **Date:**

Detail of Consignment receiver:

Name and Designation……Contact Number……

Address…….

Details of shipping items

S.N.	*Name of drugs*	*Batch number*	*Presentation*	*Quantity*	*No. of Packages*	*Shipment Route*
1						
2						
3						

Detail of person carrying the controlled substance

Name of driver/Officer and identification number (License/ CID) ……

Vehicle type and number……

Detail of issuing Authority

Dated signature of Issuing Officer OFFICE SEAL

Name: Designation:

Annexure II : Control Drugs stock register

Name of the drug:…… Presentation……Strength……
Mfg. Date:……Expiry Date:…… Batch No:…….

S.N.	Date of receipt	Qty received	Supplier information	Date of dispensing/ Issuing	Oty dispensed/issued	Stock balance	Prescribing veterinarian's signature	Recipient information	Signature