

দ্রুন্থন্বার্শ্ব বিন্যার্শনের্শ্ব ব্রিন্যার্শনের্শ্ব ব্রিন্যার্শনের্শ্ব ব্রিন্যার্শনের্শ ক্রিন্য ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture and Livestock Department of Livestock NATIONAL CENTRE FOR ANIMAL HEALTH Serbithang: Thimphu



TERMS OF REFERENCE

FOR

MANAGEMENT OF THE ESSENTIAL VETERINARY SUPPLY SYSTEM (EVSS)

2025 Edition





ਜ্রুন্থেঁদেম স্থ্রার্ব্ব শেষ্ বার্ব শের্ষ দেন স্থ্রাব্ব শেষ্ট্র বা ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture and Livestock Department of Livestock NATIONAL CENTRE FOR ANIMAL HEALTH Serbithang: Thimphu



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1. ANNUAL INDENTING

In order to receive quality medicines, vaccines, equipment and consumables, proper indenting is to be done by all the animal health facilities as per the supply chain cycle (*annexure 11.1 & 11.2*).

1.1 Objectives:

- 1.1.1 To ensure realistic indenting of veterinary medicines, vaccines and equipment.
- 1.1.2 To support the procurement and distribution of quality veterinary medicines, vaccines and equipment

1.2 Roles & Responsibilities of animal health facilities:

1.2.1 DVEU HEAD, NCAH

- The DVEU shall circulate an official communique to NVH, RLDC, RVH&EC, and DVH twice a year except in rare emergencies.
- The DVEU shall compile the national indent, verify, and finalize for procurement.
- The DVEU shall prescribe formats for annual indenting to NVH, RLDC, RVH&EC and DVH
- The total indent of medicines/Vaccines /Equipment submitted by region and NVH shall be approved by the Head of the DVEU and Upload in e-GP

1.2.2 NVH

• The NVH shall submit annual indenting to DVEU on an annual basis using the past consumption pattern, morbidity data & hospital requirements.

1.2.3 RLDC/RVH &EC

- Coordinate, compile, and verify annual indenting under their region and submit it to DVEU using department-approved software G2C or Google sheet.
- RVH & EC/ RLDC shall submit the total quantity of the drugs, vaccines required on an annual basis using the past consumption pattern, morbidity data & center requirements.

1.2.4 DVH and RNR-EC





- The DVH shall further circulate the official communique and formats of annual indenting to the RNR-EC
- The RNR-EC in charge shall determine the total quantity of the drugs and vaccines required on an annual basis using the past consumption pattern and will submit to the VO of their respective Dzongkhag.
- The DVH shall compile all annual indent, verify, and further submit to their respective regional EVSS focals.

1.2.5 Central farms/government farm

• The Central farms/Government farms shall submit annual indenting to their respective Region focal (RVH & EC and RLDC) based on the past consumption pattern, morbidity data & their farm requirements.

2. TENDERING OF VETERINARY MEDICINES, VACCINES, NON-MEDICINE ITEMS & EQUIPMENT

Quality veterinary medicines, vaccines, equipment and consumables should be procured following the financial rules and regulations of Ministry of Finance.

2.1 Objectives:

- Procurement of veterinary medicines, vaccines, non-medicines & equipment in line with the financial rules & regulations of MOF.
- To ensure transparency, accountability, and efficiency in the tendering of veterinary medicines, vaccines and equipment.
- To ensure the timely availability of quality veterinary medicines, vaccines, non-medicine items, and equipment.

2.2 Tender Committee:

The Tender Committee for Veterinary Medicines, Vaccines, Non-Medicine items & Equipment shall comprise of the following:

2.2.1 Tender Evaluation Committee

• One representative (Veterinarian) from National Veterinary Hospital, Motithang





- One representative (Veterinarian) from RVH & EC
- Two representatives (Veterinarian) from Dzongkhag Veterinary Hospital.
- Two representatives from the National Centre for Animal Health, Serbithang.
- One representative from LCS.

2.2.2 Tender Awarding Committee

- Dasho Secretary, MoAL (Chairman)
- Director, DoL, MoAL
- Chief, AHD, DoL
- One Representative, Cluster Finance Services, MoAL
- One Representative, Procurement Section MoAL
- Program Director, NCAH, Serbithang

Note: Since tendering is done through eGP system, there is no involvement of tender opening committee.

2.3 Roles and responsibilities of tender committee:

2.3.1 Tender Evaluation Committee:

- Every member of the committee should attend a pre-evaluation meeting to draw consensus on evaluation criteria.
- The member secretary shall keep minutes of evaluation committee meetings which shall be the basis of tender evaluation criteria.
- Every member of the committee must declare a conflict of interest.
- Verify the validity of the Trade License, Tax clearance certificate, and Power of Attorney of the respective suppliers.
- Verify the technical specification and check the validity of the Drug Registration Certificate and Price Schedule of drugs, vaccines, equipment, and non-drug items.
- All committee members must give priority to a valid Drug Registration Certificate holder for the selection of supplier provided the price schedule is in line with the price structure submitted to BFDA.
- The chairman must present the report to HOPA on the final day of evaluation.

2.3.2 Tender Awarding Committee

- Review the evaluation report submitted by the evaluation committee.
- Endorsement of the evaluation report.



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- Recommend for award, retender, or direct purchase or through other sources as appropriate based on the evaluation report.
- Provide other necessary recommendations as deemed appropriate.

3. VERIFICATION AND INSPECTION

After the medicine, non-medicines and equipment consignment is received at the LCS, and vaccine is received at BPU, NCAH, a team should verify and inspect the items for quality assurance.

3.1 Objectives:

- 3.2.1 To ensure the quality of veterinary medicines, vaccines, non-medicine items and equipment.
- 3.2.2 To ensure transparency, accountability, and efficiency in the procurement and supply of veterinary medicines, vaccines and equipment.

3.2 Team Composition

- 3.2.1 One representative (veterinarian) from National Veterinary Hospital, Motithang.
- 3.2.2 One representative (veterinarian) from Regional Livestock Development Centre or Regional Veterinary Hospital & Epidemiology Centers.
- 3.2.3 One representative (veterinarian) from Dzongkhag Veterinary Hospital.
- 3.2.4 One representative from National Centre for Animal Health, Serbithang.
- 3.2.5 For verification of vaccine, the team shall be comprised of unit heads from NCAH.

3.3 Roles for Drug Verification and Inspection team

- 3.3.1 A team comprising of representatives from National Veterinary Hospital, National Center for Animal Health, Dzongkhag and Livestock Center store will be instituted for verification and inspection.
- 3.3.2 A minimum of three members should be present at the time of inspection and verification.
- 3.3.3 The team members shall declare their conflict of interest prior to inspection and verification as per the form (*annexure 11.3*).
- 3.3.4 Verification and inspection of:
 - Medicine: Team shall physically inspect and verify the consignment with inspection criteria (composition, strength, specification, pack size, manufacturer, and shelf life of the medicine) as per supply order issued from DVEU.
 - Vaccines: Team shall physically inspect and verify the consignment with inspection criteria (composition, strength, specification, pack size, manufacturer, and shelf life of the medicine) as per supply order issued from DVEU.



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- Equipment and consumables: Team shall physically inspect and verify the consignment as per the inspection criteria (catalogue/sample submitted during tendering)
- For the registered product, the team shall verify the valid certificates issued by MPD (Medical products division) of BFDA.
- For non-registered products, the team shall verify import authorization.
- 3.3.5 The team shall document in detail the reason for rejection of the product if rejected.
- 3.3.6 Submits the final verification report to the Store In-charge, LCS after every verification and inspection of newly arrived consignments.

4. STORE INVENTORY MANAGEMENT AND STORAGE

The purpose of these Terms of Reference is to outline the scope and responsibilities for managing veterinary medicine, vaccines, non-drug items, and equipment inventory and storage at Livestock Central Store (LCS, Phuntsholing) and Vaccine unit (NCAH). Effective inventory management and storage is crucial for ensuring the availability, safety, and proper storage of medicines and vaccines in the medical stores.

4.1 Objectives:

- 4.1.1 To maintain adequate stock levels of essential Veterinary medicines, vaccines, nonmedicine items, and equipment
- 4.1.2 To ensure the safe and secure storage of Veterinary medicines, vaccines, non-medicine items and equipment in compliance with relevant regulations, guidelines and SOPs.
- 4.1.3 To track and manage the Veterinary medicines, vaccines and no medicine items nearing expiry, preventing the supply of expired medicines, vaccines and non-medicine items.
- 4.1.4 To optimize the use of available storage space and reduce wastage due to overstock or insufficient storage.

4.2 Roles & Responsibilities:

4.2.1 Store Officer:

- 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 proposals and disposal of expired medicines.
- Maintain a database of medicine stock inventory which would provide a real-time stock level at the LCS to NCAH.

4.2.2 Assistant Store Officer:

• Receive, inspect, verify and storage of goods.





- Supervise labeling of storerooms and shelves, storage, daily recording of temperature and humidity of rooms and refrigerators.
- Update bin card, stock register, and issue goods received notes and certify invoice received from the suppliers.

4.2.3 Store Assistant:

- Assist Assistant Store Officer in receiving of goods, inspection, storage, update bin card, stock entry and preparation of goods received note.
- Maintain daily temperature and humidity recording sheets of storerooms and refrigerators.
- Maintain data of nearing expiry medicines and submit to the supervisor for the timely mobilization.

5. DISTRUBTION AND MONITORING

Timely and rational distribution of medicines, vaccines and equipment is very much important for the animal health facilities for access.

5.1 Objectives:

5.1.1 Ensure availability of quality medicines and vaccines to all the animal health facilities

- 5.1.2 Minimizing expiry
- 5.1.3 Ensuring efficacy & safety of the medicines and vaccines

5.2 Distribution

- 5.2.1 Distribution of the medicines and equipment will be twice as per the cycle including all other relevant agencies. However, the vaccines will be distributed as and when the DVEU/BPU received requisition from animal health facilities.
- 5.2.2 The respective agencies will ensure to send one representative during medicine packaging to avoid mismatch of products and indents.
- 5.2.3 Distribution will be done till DVH and central farms level by LCS and further distribution will be done by respective dzongkhags.
- 5.2.4 The Dzongkhag EVSS focal persons will ensure segregation of the drugs, vaccines and equipment as per the gewog indent and dispatch to the centers.
- 5.2.5 The animal health focal person of central farms will ensure segregation of the drugs, vaccines and equipment as per the indent for their respective farms.
- 5.2.6 Emergency or ad hoc distribution will be made by the LCS/BPU/DVEU based on the requirements submitted by individual agency and strictly upon approval from NCAH only.
- 5.2.7 The transportation of the emergency medicines will be arranged by respective agencies.



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5.3 Monitoring

- 5.3.1 The monitoring of EVSS shall be done twice.
 - Routine annually
 - Ad hoc on demand
- 5.3.2 The Dzongkhags EVSS focal persons will monitor the LECs/RNRECs in their respective Dzongkhags and submit monitoring reports on an annual basis to regional EVSS focal persons who will compile and submit to NCAH.
- 5.3.3 The regional EVSS focal persons will monitor the DVHs, Farms and Central Agencies in their respective region and submit the monitoring reports annually.
- 5.3.4 The EVSS monitoring reports will be submitted as above for the visits and monitoring done for respective centers (not compulsory to do for every gewog centers/farms/CAs in the respective Dzongkhags or region).
- 5.3.5 The monitoring reports will be submitted in the standard formats developed by DVEU.
- 5.3.6 Monitoring may be done for other agencies (e.g CNR, wildlife, NBC etc.) if required.

6. MOBILIZATION OF NEARING EXPIRY DRUGS AND VACCINES

Mobilization of drugs and vaccines nearing expiry to the other animal health facilities requiring the medicine is one of the main ways to reduce expiry losses.

6.1 Objectives:

- 6.1.1 To reduce wastage of medicines, vaccines and financial resources.
- 6.1.2 For effective usage of medicines, vaccines and consumables.

6.2 Roles of different facilities

6.2.2 Livestock Central store:

- The store in charge shall check the expiry date of medicines on regular basis.
- The store in charge shall compile the list of drugs nearing expiry (3 months) and submit on monthly basis to NCAH.
- LCS shall facilitate to issue/ mobilise the medicines according to the approved requisition from NCAH submitted by DVHs and central agencies.

6.2.3 DVEU, NCAH:

- DVEU shall compile all the reports received from LCS on monthly basis.
- Based on the report from LCS, NCAH shall notify regional agencies/ Dzongkhags/Central agencies with instruction to mobilize/put requisition.
- DVEU shall issue order to mobilize medicines, vaccines, equipment and consumables based on the requisition/ indent received from dzongkhags and central agencies.





6.2.4 RLDC/ RVH-EC:

- Shall compile the list of medicines and vaccines nearing expiry received from DVHs.
- Shall mobilise the medicines and vaccines nearing expiry within its region based on the requirement.
- Shall submit the list of medicines and vaccines nearing expiry to NCAH if they cannot mobilize within their jurisdiction.

6.2.5 Dzongkhag Veterinary Hospitals/ Central agencies

- Shall compile the list of medicines and vaccines nearing expiry from RNR-ECs/ LECs on bimonthly basis and submit to respective RLDC/ RVH EC/ NCAH
- Mobilise the medicines and vaccines nearing expiry within its dzongkhag.
- Submit the list of medicines and vaccines nearing expiry to RLDC/ RVH-EC if they cannot mobilize within their jurisdiction.
- DVHs in Paro, Haa, Gasa, Wangdue, Thimphu and Punakha, and National veterinary Hospital, central farms (NDDC, RPBC, Masti Farm, Yak farm, NNPBC, RPBC) shall submit list of medicines and vaccines nearing expiry to NCAH.

6.2.6 Renewable Natural Resources Extension centres:

• RNR-EC shall submit list of medicines and vaccines nearing expiry DVH on bimonthly basis.

7. MANAGEMENT OF EXPIRED MEDICINES AND VACCINES

It is important to manage the expired medicines and vaccines and dispose off properly following the administrative and financial approval and NEC guidelines.

7.1 Objectives:

• To manage and dispose the expired medicines and vaccines safely.

7.2 Segregation of expired Medicines:

- 7.2.1 Store the medicines and vaccines in first expiry first out (FEFO) method.
- 7.2.2 Segregate the expired medicines and vaccines.
- 7.2.3 Segregate the expired medicines and vaccines as Hazardous and non-hazardous waste. (Refer the Guideline for disposal of pharmaceutical waste 2014 by the Medical Product Division (MPD) under Bhutan Food and Drug Authority (BFDA) for further information.
- 7.2.4 Collect of hazardous medicines and vaccines as and when required by DVHs/ RLDC/ RVH&ECs/ NCAH /LCS.



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- 7.2.5 Regional EVSS focal persons should be informed on expired medicines and vaccines in the Dzongkhag for monitoring.
- 7.2.6 DVO/DVH in-charge should monitor and collect information on expired drugs and vaccines from their Geogs.

7.3 Administrative & Financial approval:

- 7.3.1 Prepare list of expired medicines and vaccines with cost.
- 7.3.2 For DVH/Gewogs submit note sheet to DLO to seek for write-off approval from Dasho Dzongda or Department based on the level of financial authority.
- 7.3.3 For the NVH/RLDC/RVH & ECs/LCS/Centre Agencies/Central farms, the write off approval may be sought from the Director DoL or Secretary based on the level of financial authority.

7.4 Transportation at Disposal Site (After write-off approval)

- 7.4.1 The non-hazardous expired medicines and vaccines could be disposed of as per the relevant MPD/BFDA & National Environment Commission (NEC) waste management guidelines by informing MPD (BFDA).
- 7.4.2 The Geog in-charges should submit the expired hazardous medicines and vaccines to DVO/DVH in-charge.
- 7.4.3 The DVO/DVH in-charges should submit the expired hazardous medicines and vaccines regional EVSS focal institutes (RLDC/RVH & EC).
- 7.4.4 The Central Farms/Central Agencies should submit the expired hazardous medicines and vaccines to respective regional EVSS focal institutes (RLDC/RVH & EC) for further disposal.
- 7.4.5 The DVHs/CAs/CFs who does not fall under EVSS focal and RLDC/RVH&EC should submit the expired hazardous medicines and vaccines to NCAH.
- 7.4.6 The collected hazardous medicines and vaccines will be stored safely at Livestock Central Store (LCS), Phuntsholing until transported to disposal site.
- 7.4.7 The hazardous expired medicines and vaccines are transported to the disposal site from LCS, Phuntsholing in presence of official from Medical Product Division (MPD), BFDA by NCAH and LCS.
- 7.4.8 NCAH/LCS will liaise with MPD, BFDA to facilitate disposal of hazardous medicines and vaccines.

8. EMERGENCY SUPPLIES OF VETERINARY MEDICINES, VACCINES, NON-MEDICINE ITEMS & EQUIPMENT

Emergency supplies of veterinary medicine, vaccines and non-medicine items involve obtaining indent and distributing swiftly and efficiently in case of an unprecedented animal disease



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outbreak. This process is crucial in ensuring that animal healthcare facilities have the necessary medicines and vaccines readily available to respond to unprecedented animal disease.

8.1 Objectives:

Swift delivery of crucial veterinary medicines, vaccines and non-medicine items to safeguard and treat animals in supporting animal health and welfare during emergency situations.

8.2 Roles and responsibilities

8.2.1 Livestock Extension Center (LEC) In charge/ Government Farms.

• Submit the list of emergency veterinary medicines, vaccines & non-medicine items required immediately to the Dzongkhag Veterinary Officer (DVO), Dzongkhag Veterinary Hospital (DVH) when essential medicines and non-medicine items are sufficient for one week at the LEC store.

8.2.2 Dzongkhag Livestock Sector

- DVO/DVH shall mobilize the indented emergency medicine, vaccines & non-medicine items from the available stock within the Dzongkhag.
- If not available within the Dzongkhag, rationalize/prioritize and submit the indent within 1 day to the National Centre for Animal Health (NCAH) with a copy to the Livestock Centre Store (LCS), RVH & EC, and RLDC.
- Dzongkhag Livestock Sector (DLS)/ Farm management to make prompt necessary transport arrangements for the lifting of drugs from LCS within a day after receiving confirmation of medicine packed at LCS.

8.2.3 RLDC and RVH&EC

- Upon receipt of the copy of the emergency requisition, facilitate mobilization from the mandated region based on availability to meet urgent requirements.
- The Regional Director/Regional Veterinary Officer of the region shall work closely with the Dzongkhag Livestock Sector to make necessary arrangements for the transportation of medicines, vaccines and non-medicine items from LCS to Dzongkhag.

8.2.4 NVH:

• Submit the list of emergency veterinary medicines, vaccines & non-medicine items required immediately to NCAH.

8.2.5 DVEU, NCAH, Serbithang

• Issue distribution order to LCS *within three days* of receiving the indent and validation of the indent.



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- If the emergency veterinary medicines, vaccines and non-medicine items are not available at LCS, NCAH or not on the tender list; NCAH, Serbithang to process *import authorization with BFDA, MoH within three days of receiving the indent.*
- Process for direct procurement (approval and liaising with the distributors) as per the SOP for Direct Procurement of Veterinary Medicines, Vaccines, Equipment and Consumables.

8.2.6 Livestock Centre Store (LCS, Phuntsholing)

- Packing and supply of the emergency medicines and non-medicine items as per the distribution list within one day of receiving of distribution order from NCAH.
- Inform the concerned official to arrange transportation and prompt lifting of the emergency medicines and non-medicine from LCS.

9. ESSENTIAL VETERINARY SUPPLY SYSTEM (EVSS) FOCAL POINTS

In order to monitor the EVSS efficiently, identifying the focal points and assigning the respective regions is very crucial.

9.1 Objectives:

> To ensure proper monitoring of the EVSS at all levels of users

9.2 EVSS focal points

- 9.2.1 By default, National, Regional and Dzongkhags centers will be the focal points for the EVSS.
- 9.2.2 The focal point for pharmacovigilance shall be the National Veterinary Hospital
- 9.2.3 National and regional EVSS focal persons shall be the Head/ In charges of DVEU/NVH/RLDC/RVH & ECs below:

Region	Dzongkhags	EVSS Focal Person	Agency
South-west	Samtse, Chukkha, central farms	RVO	RVH & EC, Phuntsholing
Central	Bumthang, Trongsa, Zhemgang, Sarpang, Tsirang, Dagana, central farms	RVO	RVH & EC, Gelephu
North-east	Trashigang, Tashiyagntse, Monger, Lhuntshe	RD	RLDC, Trashigang
South-east	Pemagatshel, Samdrupjongkhar, central farms	RVO	RVH & EC, Dewathang



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North-west	Thimphu, Haa, Paro, Punakha, Wangdi, Gasa, central farms	Head	DVEU, Serbithang
Pharmacovigilance for whole country	All 20 dzongkhags & central farms	Head	NVH, Motithang

Note: Animal health in-charges of the central farms will be focal points for EVSS

9.3 Roles of different EVSS focal points

9.3.1 Dzongkhag EVSS Focal Persons

- By default, the DVOs or DVH In-charges will be the EVSS focal person of the concerned Dzongkhag including central farms.
- Provide technical backstopping to the LECs/RNRECs/Farms regarding use of medicines and vaccines.
- > Involve during the time of national drug review (addition and deletion ddrugs).
- Timely monitoring and evaluation of drugs, vaccines and equipment in the LECs/RNRECs/Farms.
- Provide refresher course to the field colleagues especially with regard to compounding and usage of the non-patent drugs at regular interval in consultation with RVH & EC.
- > Intra Dzongkhag drug and vaccine mobilization including farms.
- Collect annual drug, vaccines and equipment indents/requisitions from their respective LEC /RNR-EC/farms and compile and submit to regional EVSS focal points.
- LECs/RNRECs/farms and compile and submit to the dzongkhag EVSS focal points and dzongkhag focal points compile and submit to regional EVSS focal points.
- Reception, verifying and collection of drugs and vaccine once it arrives in DVH from LCS and segregate and distribute further as per the gewog drug indent.
- For central farms, animal health in-charge will be responsible for indenting, receiving, and verifying drugs, medicines, vaccines or equipment for their respective centers.
- The respective EVSS focal person from the dzongkhag to be present at LCS during drug distribution for verification of the indents/requisitions for their respective dzongkhag

9.3.2 Regional EVSS Focal Persons





- Co-ordinate and bridge a linkage between NCAH, RVH-EC, Center farms and DVHs
- Compile, verify and submit the drug indent to NCAH.
- > Update and synchronize the drug indenting format in the region.
- > Collect and compile the drug reports as and when required.
- > Initiate and follow up on the inter and intra dzongkhag drug mobilization.
- Monitor and standardize the EVSS at DVH and LECs/RNRECs.
- Technical backstopping on the drug usage, storage, formulary, and proper dispensing at the center and Dzongkhag level.
- Maintain buffer stock of drugs and vaccines to be supplied during times of emergency.
- Regulate and ensure minimum standards in compliance with the DRA norms with feedbacks and recommendations.
- Monitor effective maintenance of expired drugs inventory.
- Ensure proper disposal of expired drugs and vaccines after collecting from regional centers with fulfillment of the required DRA regulations and procedures before disposal.
- Scrutinize on failing to meet the minimum requirements upon inspection.
- > Performing surprise inspection of stock of drugs and equipment in the region.
- Coordinate and lead the supervision during drug, vaccine and equipment inspections/verifications and during packing and distribution of drugs and equipment.

10. NATIONAL VETERINARY MEDICINE COMMITTEE (NVMC)

As provisioned in Medicines Act of Kingdom of Bhutan 2003, the first technical committee on veterinary drugs were formed and named as National Veterinary Drug Committee (NVDC) during 2010-11. The committee members are comprised of representatives from relevant stakeholders under the Department of Livestock and co-opted members from relevant agencies dealing with Veterinary medicine, biological, veterinary equipment and non-medicine. This was the highest technical advisory body on matters related to essential veterinary drug program for the Department of Livestock in Bhutan.

The members, mandates & roles of the committee were reviewed and updated during 2014-15 at the 7th NVDC Meeting. Later, the NVDC was renamed as Scientific and Technical Advisory



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Committee on Veterinary Medicines (**STAC-VM**) during the 9th NVDC meeting. The main objective of renaming was for alignment of the nomenclature to its technical functions as envisaged by World Organization for Animal Health (OIE). Again, during March 2019, the members unanimously resolved to rename the committee as **National Veterinary Medicine Committee** (**NVMC**) during the 11th NVMC meeting. The replacement of drug with medicine was in line with international norms and practices.

10.1 Composition of the Committee

10.1.1 **Permanent members**

- 1. Chief Veterinary Officer, Animal Health Division- (Permanent Member)
- 2. Program Director, NCAH (Permanent Member)
- 3. Head, NVH, Motithang, (Permanent Member)

10.1.2 **Co-opt Members:**

- 1. VOs, DVH (1 VO from each region)
- 2. RD, RLDC, RLDC Kanglung (Member)
- 3. RVO, RVH & EC Dewathang (Member)
- 4. RVO, RVH & EC Gelegphu (Member)
- 5. RVO, RVH & EC Phuntsholing (Member)
- 6. PD, NRDCAN, Bumthang
- 7. Animal Health incharge, Fishery commodity center
- 8. Animal Health incharge, piggery commodity center
- 9. PD, NDRC, Yusipang
- 10. Health In-charge, RPBC, Paro
- 11. Health in charge, wildlife
- 12. Representative from Medical Products Division, BFDA, MOH
- 13. Pharmacovigilance focal, NVH
- 14. PD, NHDC, Wangduephodrang
- 15. In charge, LCS, Phuntsholing
- 16. Animal Health In charge, wildlife
- 17. Representative, Livestock Extension Centre
- 18. Head, BPU, NCAH Serbithang

10.1.3 Member Secretary

• Head DVEU

10.2 Functions of the Committee

The Committee shall act as a scientific and technical advisory body to the Department of Livestock, Ministry of Agriculture & Livestock on matters related to essential veterinary drug program as follows:



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- 10.2.1 Provide technical guidance to DVEU on matters related to EVSS such as rational use of medicines and equipment, quality and safety assurance, selection of pharmaceuticals, drug testing, emergency procurement, and other technical matters.
- 10.2.2 Advise relevant agencies and set the minimum standard requirements for clinical service facilities at different levels in the country.
- 10.2.3 Review and endorse EVD list once every two years or as deemed appropriate by the NVMC Secretariat
- 10.2.4 Review, recommend and endorse National Veterinary Drug Formulary (NVDF) once every two years.
- 10.2.5 Review, recommend and endorse standard guidelines related to EVSS such as Standard Treatment Guideline (STG), Antibiotic Guidelines, Anti-microbial resistance control strategy document, Adverse drug reactions (ADR) and biological guidelines etc.
- 10.2.6 Endorse the categorization and standardization of medicines, biologicals, and veterinary equipment for different animal health facilities in the country.
- 10.2.7 The committee shall liaise with relevant agencies to update and advice the Department on controlled and banned veterinary medicines.
- 10.2.8 Advise relevant agencies and endorse permissible limits of animal feed pre-mixes and additives, in-house production/import of feed ingredients and its regulation.
- 10.2.9 The committee shall review and endorse national animal feed standards and advise on feed testing.
- 10.2.10 Provide technical guidance to the National Antimicrobial Technical Committee (NATC) on matters related to Antimicrobial Resistance (AMR) and their control in veterinary practice.
- 10.2.11 Provide technical guidance to relevant agencies on anti-microbial residues on animals, animal products and feeds.
- 10.2.12 The committee shall review and endorse the research activities proposed by relevant agencies related to drug efficacy, quality, and safety.
- 10.2.13 Review and advice relevant agencies on public private partnership (PPP) on the sale of selected list of veterinary medicines in retail pharmacies
- 10.2.14 Act as an interim advisory body in absence of veterinary statuary body/veterinary council on the matters related to veterinary clinical practice.

10.3 Roles and responsibilities of committee members

- 10.3.1 As per the recommendations by the NVMC, shall represent for sub-committee as and when required to work on emerging issues related to EVSS.
- 10.3.2 The relevant NVMC members shall lead and coordinate the sub-committee as below:
 - STG, standard Clinical Service Facilities NVMC member from National Animal Hospital
 - Antibiotic usage guidelines, AMR issues- AMR focal point
 - Feed pre-mixes, feed standards, feed testing-NVMC member from NRCAN
 - Veterinary Biologicals- NVMC member from BPU
 - Veterinary medicines, equipment and non-medicine items, formulary, EVDL list-National EVSS focal point.



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10.3.3 Any other areas which require formation of sub-committees shall be led by relevant member or agency.

10.4 Tenure of the Committee

- 10.4.1 The NVMC members shall be proposed by NVMC secretariat to the committee for review and endorsement.
- 10.4.2 The Department shall approve the committee members based on the recommendation and endorsement of the NVMC meetings.
- 10.4.3 The members shall be revised once in two years.
- 10.4.4 The proportion of old NVMC members retained in the reconstituted committee shall be a minimum of 50%.

10.5 Meeting

- 10.5.1 The Committee shall meet at least once a year or as and when required.
- 10.5.2 The members who are unable to attend the NVMC shall delegate representatives on his/her behalf
- 10.5.3 The meeting shall be convened as deemed appropriate by the NVMC secretariat.
- 10.5.4 Two-third quorum is required to make decisions.
- 10.5.5 The decisions of the meeting shall be based on simple majority.
- 10.5.6 All decisions of the meeting shall be recorded and maintained by the NVMC secretariat.

10.6 Responsibilities of Chairman

- 10.6.1 Chair and moderate the Committee meetings.
- 10.6.2 Convene NVMC meeting during emergencies.
- 10.6.3 Make decisions based on the technical views and recommendations of the NVMC members.
- 10.6.4 Take relevant issues to concerned agencies or bodies for further deliberations such as DTAC and the Department.
- 10.6.5 Approve the minutes of the meetings and direct the secretariat for circulation and follow up actions.
- 10.6.6 Chairman shall designate a representative among the committee members in his absence) to function as the chairman (only during emergency meetings).
- 10.6.7 Decide to convene meeting even if two-third quorum is not present during emergencies.
- 10.6.8 Chairman of NVMC will be the ex-officio member of Drug Technical advisory Committee (DTAC).

10.7 Tenure of Chairman

- 10.7.1 The Chairman shall serve for a term of two years.
- 10.7.2 The Chairman shall not serve for more than two terms consecutively.



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10.8 Roles of NVMC secretariat

- 10.8.1 The DVEU shall be the secretariat to NVMC and the head of DVEU shall be the member secretary to the committee.
- 10.8.2 The member secretary is **<u>not</u>** an NVMC member.
- 10.8.3 Coordinate and organize NVMC meetings/ emergency meetings.
- 10.8.4 Record the minutes of the meeting, circulate and follow-up on the minutes.
- 10.8.5 Collect issues related to EVSS from the field and put them up in the NVMC meetings.
- 10.8.6 Propose revision of the NVMC members, put up to the committee for review and obtain approval from the Department.
- 10.8.7 Conduct selection of NVMC chairman through fair process.

10.9 Selection/Election Procedure

- 10.9.1 Chairman shall be selected from the three permanent members (Chief, AHD, PD, NCAH, Head, NVH).
- 10.9.2 A chairman shall be a veterinarian who is technically sound in veterinary medicines and clinical practice.

10.10 Code of Conduct

- 10.10.1 All the NVMC members shall conduct in an ethical and professional manner throughout the proceedings.
- 10.10.2 Any NVMC members having any conflict of interest on matters discussed in the meeting shall abstain from attending the meetings.
- 10.10.3 All the members shall try to attend the meetings.

10.11 Revision on Mandates and Functions

- 10.11.1 Any revision to these mandates and functions of the Committee shall be proposed by the NVMC secretariat to the Department based on emerging needs.
- 10.11.2 The NVMC shall review and revise the mandates and functions of the committee as and when required.



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11. ANNEXURES

11.1 Supply Chain Cycle for Medicine & Vaccines







ক্রুন্সথ্যদেশ স্থ্রার্বি শের্গ দেশ স্থ্রান্দ শ্রের্গ দেশ স্থ্রান্দ শের্গ স্থ্রা স্থ্রান্দ স্থ্রা স্থ্রা স্থ্রা ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture and Livestock Department of Livestock NATIONAL CENTRE FOR ANIMAL HEALTH Serbithang: Thimphu



11.3 Conflict of Interest form

DECLERATION OF INTEREST AND CONFIDENTIALITY

DRUGS VACCINES & EQUIPMENT UNIT, NATIONAL CENTER FOR ANIMAL HEALTH, SERBITHANG

I....., (AGENCY.....,

declare that to the best of my knowledge, I do not have:

- any financial interest in the suppliers for the Subject
- any immediate relatives or close friends with a financial interest in the Subject
- any personal bias or inclination which would in any way affect my decisions in relation to the Subject
- any personal obligation, allegiance or loyalty which would in any way affect my decisions in relation to the Subject

I also declare that in the decisions leading to this approach to market, I have not made recommendations or decisions that may have been impacted by any perceived or actual conflicts without first having declared those conflicts.

I undertake to make a further declaration detailing any conflict, potential conflict or apparent conflict which may arise during verification and evaluation of the consignment. I agree to abstain from any decision where such a conflict arises.

I agree to keep all information and documents relating to verification and inspection process confidential, and not to disclose or communicate the same to any person or persons except in the course of my duties without the prior written approval from DVEU.

I agree not to make copies of or take any extracts of information except as may be necessary and essential for the due and proper performance of my duties.

I agree to comply with all processes and protocols established by NCAH to maintain the confidentiality of information and documentation relating to verification and evaluation of the consignment.

I acknowledge that breach of confidentiality and unauthorised disclosure are subject to the provisions and penalties contained in existing legislation.

This declaration is made by me on the understanding that I will not be taken to have breached its terms if I am legally required to disclose the information referred to.

Signed			
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Dated/..../...../