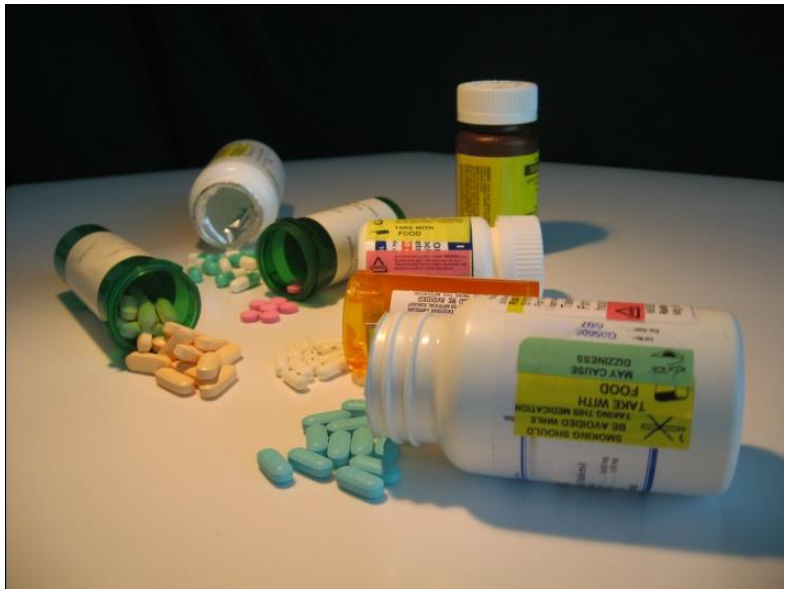
Country Experiences of Centralised System of Veterinary Medicines Procurement, Distribution, and Monitoring



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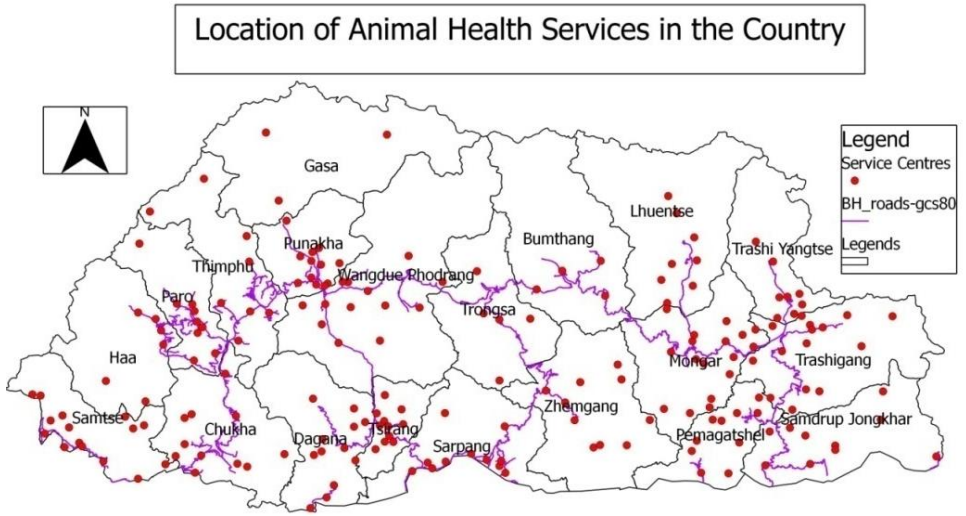
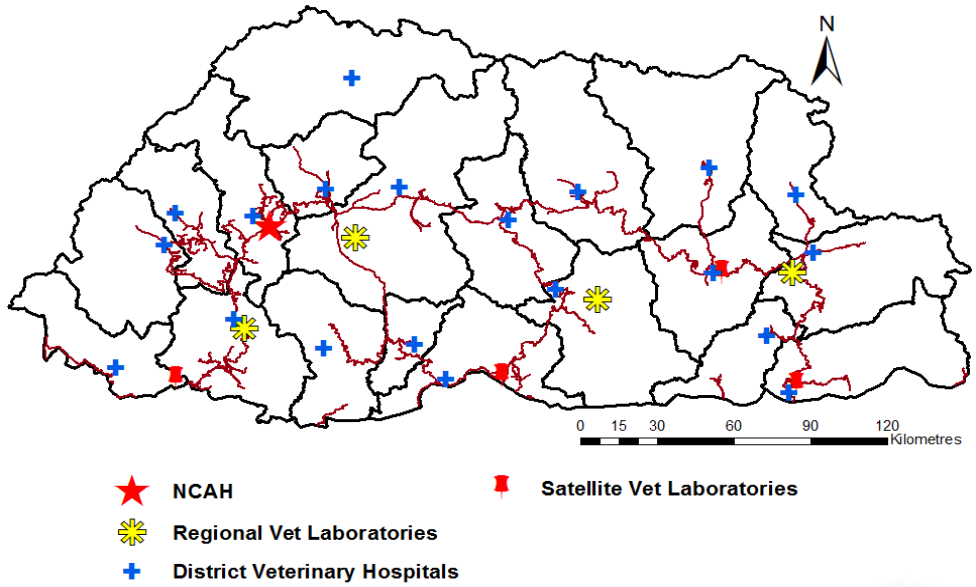
Introduction

- Animal health services – free of cost through 224-animal health service centres, 4 regional centres, one national centre
- Treatment, vaccination, laboratory diagnostic services





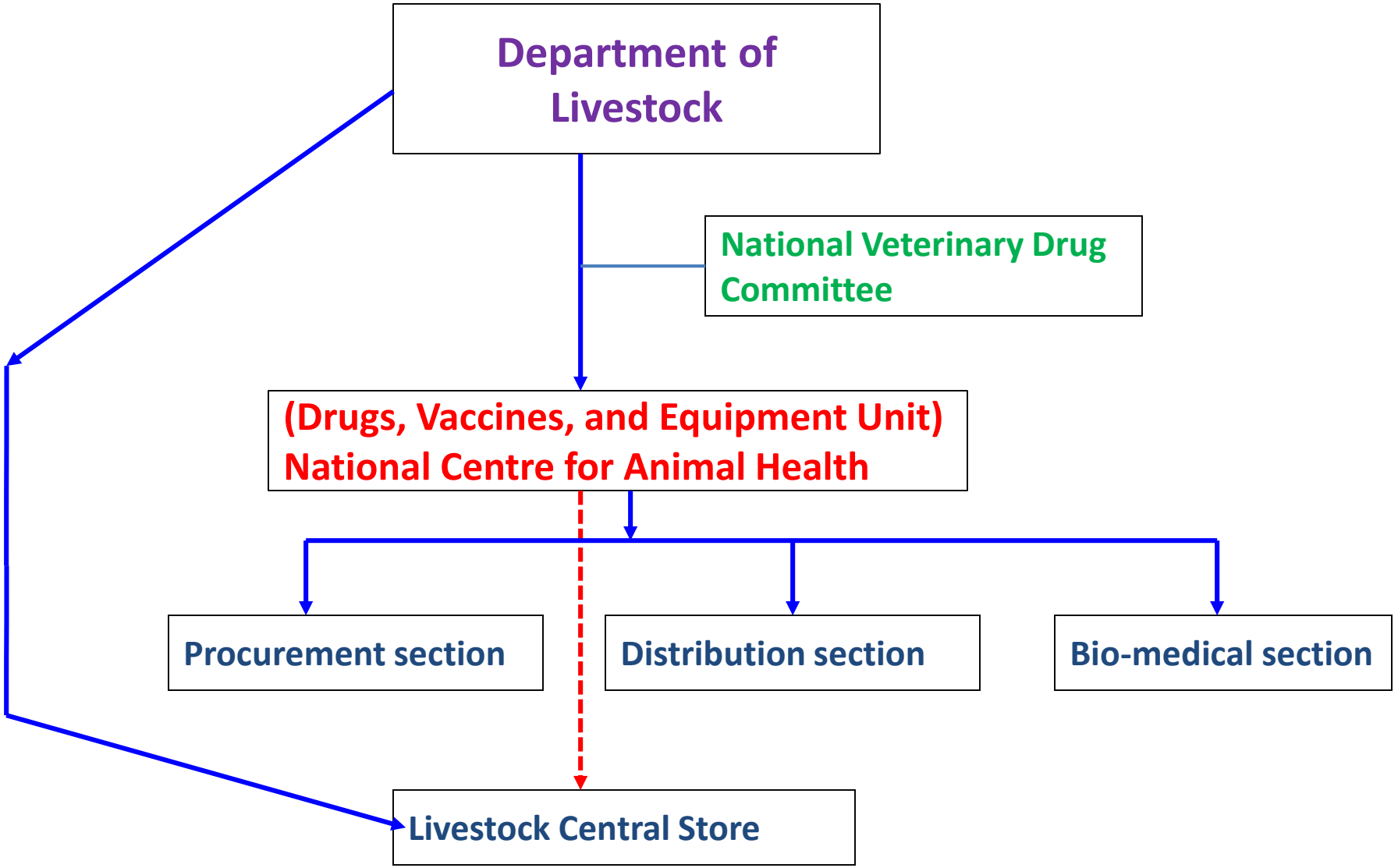
Essential Veterinary Drug Program (EVDP)

- Program for overall management of veterinary drugs, equipments, and vaccines

- EVDP implemented by Drugs, Vaccine and Equipment Unit (DVEU).

- DVEU housed at NCAH under Department of Livestock and functions in collaboration with Livestock Central Store/RLDCs/Districts/Blocks

Organizational set up



Mandates of DVEU

Timely procurement of veterinary medicines, vaccines & equipments

- Monitoring drug/vaccines/equipment supply, usage, and feedback
- Maintenance of veterinary equipment & cold chain equipments
- Organize trainings/meetings on EVDP
- Organize NVDC meetings
- Liaise with DRA and take follow-up action in regards to drug inspection reports.

Essential Veterinary Drug Program

- EVDP managed by the then Department of Animal Husbandry.
- From 1993 to June 2010, decentralized system (Dzongkhags proposed budget for medicine procurement)
- Procurement/supply order by AFD and Department
- Dzongkhag submit demand draft for procurement
- Livestock Central Store issued medicines of equivalent amount of draft.
- Transportation arranged by Dzongkhags & Central farms
- Quality assurance poor – no drug regulation
- Poor monitoring
- Drug expiry problems

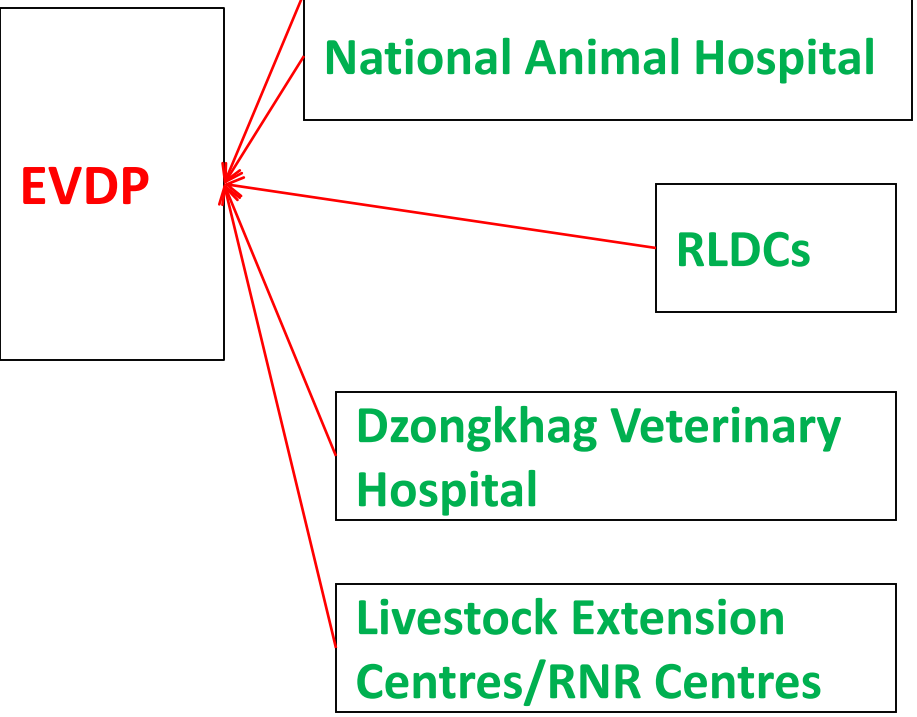
Current set up of EVDP management

- Current system in operation since July 2010.
- Procurement and distribution of drugs centralized as approved by the cabinet.
- Drugs, Vaccines and Equipment Unit (DVEU) created as one of the functional units at NCAH (2010-11 FY).

Objectives of EVDP

- Ensure availability of quality veterinary drugs, vaccines and equipments consistently in the country.
- Procurement of veterinary drugs, vaccines and equipment in line with the Procurement rules and regulations 2009 in the most transparent, systematic, scientific and efficient way.
- Rational distribution of drugs, vaccines and equipment to animal health facilities and central units.
- Delivery of quality animal health services through provision of quality veterinary drugs, vaccines and equipment.

Functions of various stakeholders within EVDP set up



Support in budgeting sourcing, fund mobilisation , tendering process

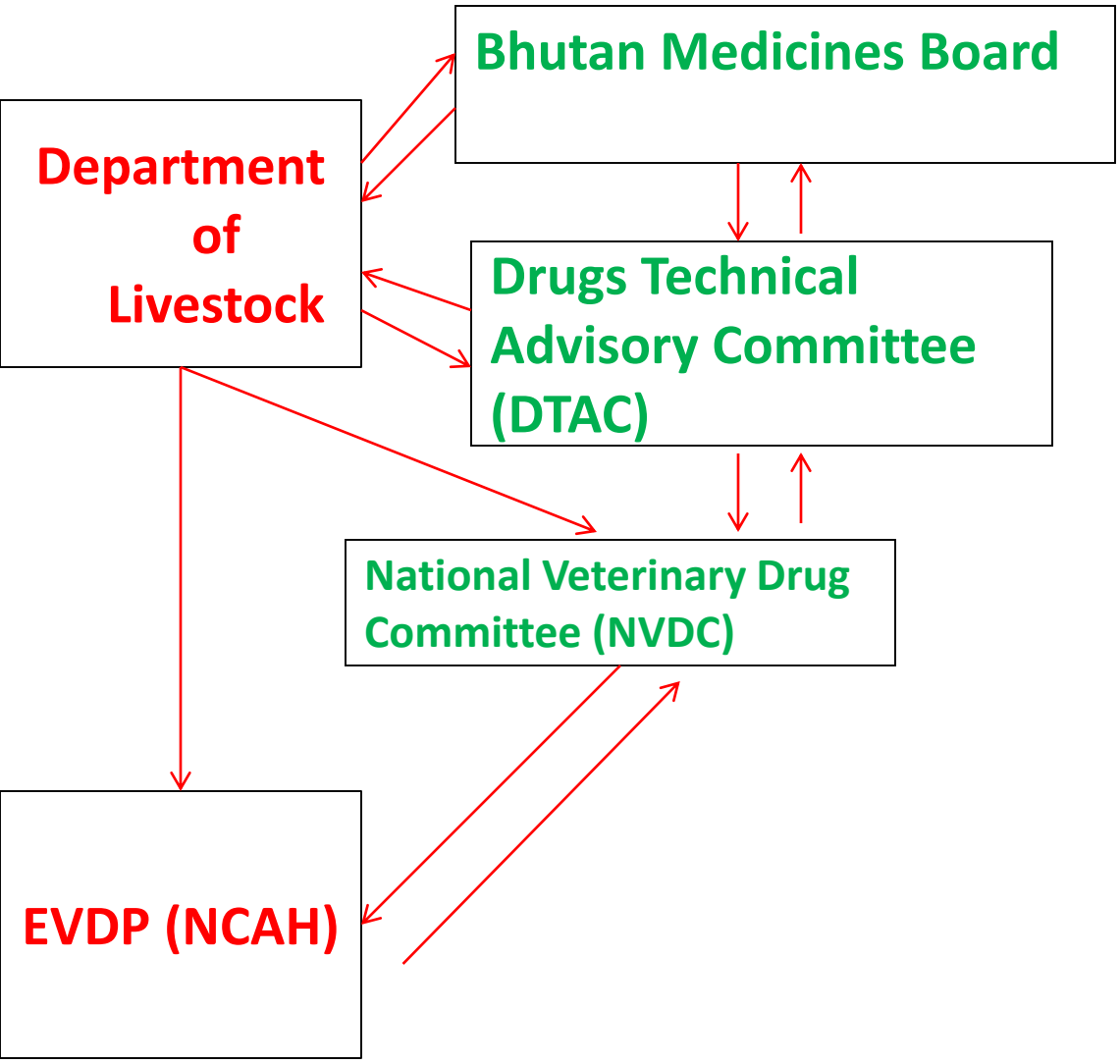
Technical apex centre for all matters on veterinary drugs. National reporting centre for adverse drug reactions/drug efficacy

Technical backstopping and monitoring of EVDP at the regional level

Drug indenting, monitoring and reporting on EVDP at Dzongkhag level
Reporting adverse drug reaction

Drug indenting, monitoring, and reporting on EVDP at Geog level
Reporting adverse drug reaction

Support to EVDP

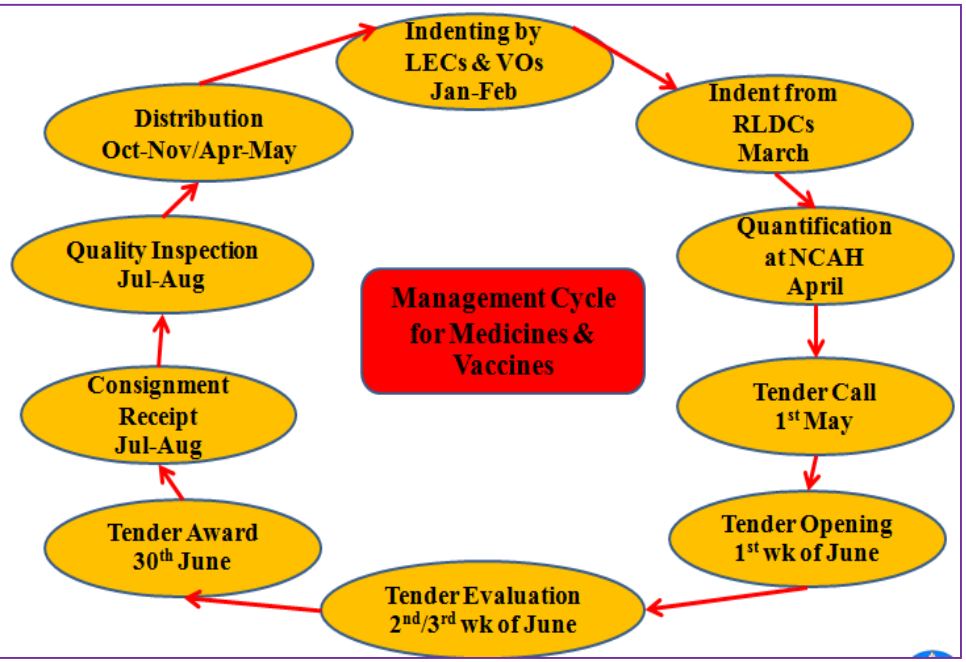


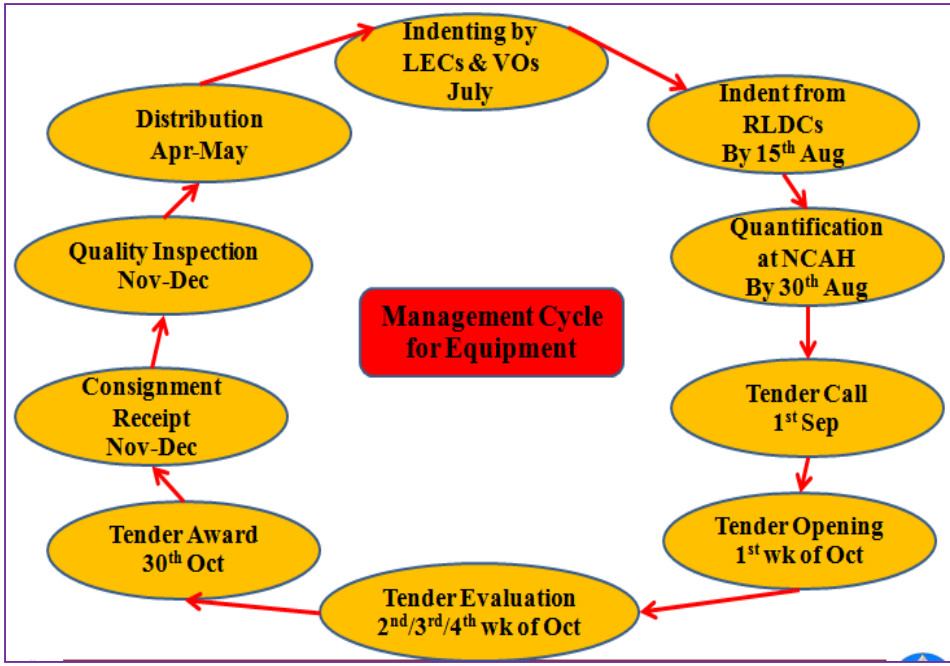
Policy decisions on manufacture, import, sale, and distribution of medicinal products including veterinary drugs

Advise the Board on all technical matters related to medicinal products and others as required by the Board

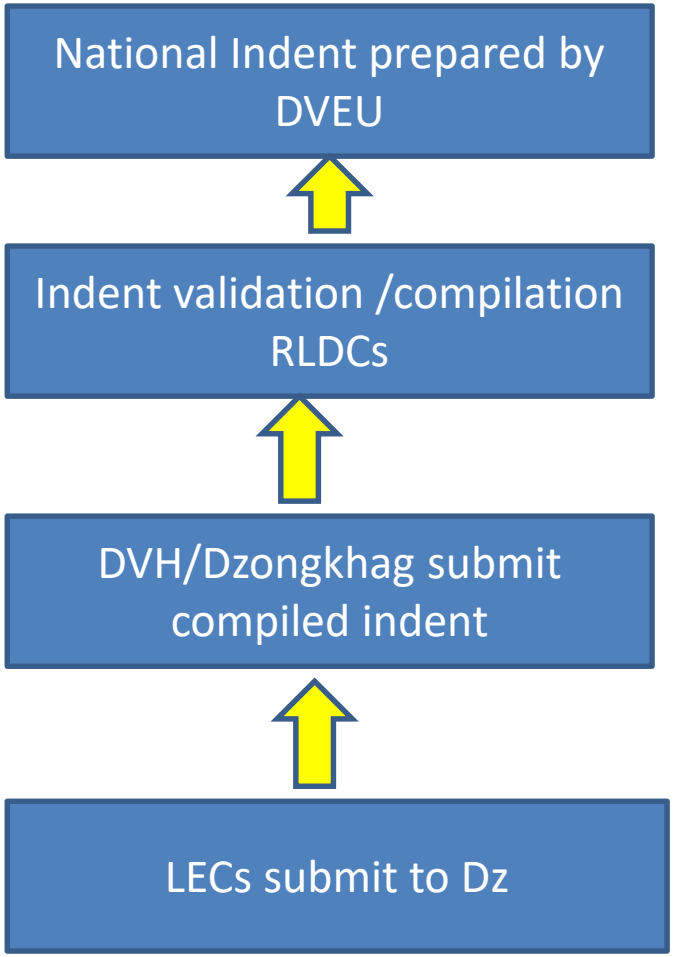
Technical decisions/recommendations on all matters related to veterinary drugs

EVDP management cycle





Drug indenting process



Basis

past consumption, standard drug list, stock balance, livestock population, disease status,

Frequency- Annually.

Regional and Dzongkhag EVDP Focal Persons

Region	Focal person	Agency
Western	Dr. Chendu Dorji	RLDC, Tshimasham
Eastern	Dr. Sangay Letho	RLDC, Kanglung
East-Central	Dr. Tshewang Gembo	SVL, Gelephu
West-Central	Dr. Rinzin Pem	RLDC, Wangdue

Drug Tendering Process

Stages	Time period	Responsibility
Tender Award	July	Awarding committee
Tender Evaluation	May/June	Evaluation committee
Tender Opening	April	Opening committee
Tender preparation and invitation	March/April	DVEU (NCAH)

Drug receipt, verification, storage and distribution

Stages	Responsibility	Remarks
Drug distribution	LCS/NCAH	distribution in Nov/Dec, geog-wise packing
Stock entry and storage	Livestock Central Store	random sampling and testing by DRA
Drug verification	Verification Committee	DRA also included in verification process
Drugs received at LCS	Livestock Central Store	

Drug shortage Issues

A. Intrinsic factors

1. Poor indenting/monitoring system/database at all levels (national, regional, dzongkhag, and geog).

B. Extrinsic factors

1. Inadequate budget versus much higher increase in livestock population.
2. Non-supply in time by the suppliers.
3. Drug registration – steep increase in price/monopoly.
4. Non registration of some drugs.

Interventions made

1. Mobilising budget from other sources – projects
2. Maintaining medicine buffer stock at RLDC Kanglung (eastern region)
3. Procurement of non-quoted drugs through MoH
4. Consideration from DRA for non registered products (Import Authorization)
5. Facilitated setting up private veterinary outlets for sale of basic medicines under Public Private Partnership (PPP) approach
6. Since 2011-12, budget for equipment segregated from medicines.
7. 2014-2015 FY, medicine and vaccine budget segregated

Interventions made

- Registration of local vaccines under process.
- Regular training of staff on GMP by DRA.
- Launch of **Government 2 Citizen database for Veterinary medicine**
  - The development of Database in the final stages

Monitoring of VMP by Drug Regulatory Authority

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Dy. Chief Regulatory Officer (Head, Inspection Division)
Drug Regulatory Authority

Mission and Vision of DRA

Vision

The most dynamic, reliable and client-centric model regulatory organization.

Mission

Promoting availability of quality, safe, and efficacious medicinal products for consumers.

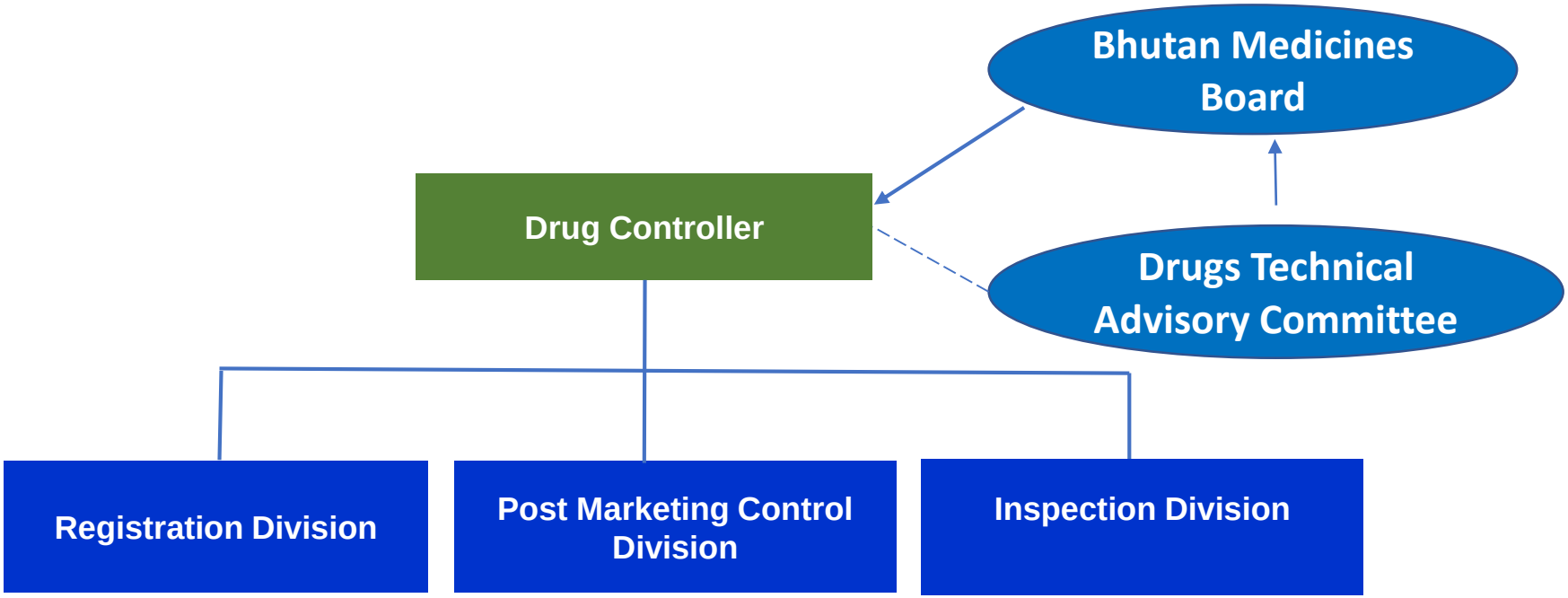
Consequences of weak/no regulation of veterinary medicinal products (VMPs)

- Import and use of Substandard and Falsified (SF) VMPs
- Inadvertent use of medicated feed without realizing the antimicrobial contents
- Self medication, irrational prescription and OTC sales of antibiotics
- Overuse of antimicrobials, treatment failure thus economic burden to the government
- Thus need for regulation

Medicines legislation

- The Medicines Act of the Kingdom of Bhutan 2003
- The Bhutan Medicines Rules and Regulations 2012 and 2019
  - Detailed procedures for regulating medicines— requirements for registration, technical authorization, manufacturing, Adverse Drug Reaction (ADR)
  - Specific guidelines drawn
- National Drug policy

DRUG REGULATORY AUTHORITY: Organizational Structure and Staffing



Role of DRA in regulating veterinary medicinal products (VMPs)

- Premarketing control
  - Authorization/registration of VMPs (safety and efficacy, prohibition of banned products, Fixed Dose Combinations (FDCs)
  - Competent Person (ex. authorized personnel)
  - Licensing of premises for sale and dispensing of medicines (Competency and Proficiency)
  - Issuance of Import Authorization (prevent SF)

  - Approval of manufacturing plants and list of products to be manufactured

Role of DRA in regulating VMPs

- Post Marketing Control
  - Inspection and surveillance (regulatory and good practices compliance, monitor storage/dispensing practices and conditions, defective products and pharmacovigilance)
  - GMP Audit of manufacturing facility
  - Restriction/prohibition of antimicrobials for non-therapeutic reasons (ex. in supplements)

Role of DRA in regulating VMPs

- Post Marketing Control
  - Quality Control - testing
  - Promotion of drug control activities (advertisement)
  - Drug information and advocacy (sensitization and BNF)

Regular monitoring of facilities to ensure compliance to the good manufacturing practices

Role of private sectors

- Use approved products/ from approved sources
- Follow good storage and transportation practices
- Sale antimicrobials against valid prescription with proper counselling
- Maintain and submit records on antimicrobials

Challenges

1. Limited quantity thus less registration

2. Sale and use of antibiotics and medicines by farm owners and farmers

3. Import for personal consumption across the border

4. Collaboration with stakeholders