Royal University of Bhutan

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College of Natural Resources

"Centre of Excellence for Rural Development Services"

NON-PATENT DRUG USAGE IN VETERINARY PRACTICE OF BHUTAN

In partial fulfillment of the requirements of B.Sc. Animal Science Programme

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DECLARATION

I declare that this is an original work and I have not committed, to my knowledge, any academic dishonesty or resorted to plagiarism in writing the dissertation. All the sources of information and assistance received during the course of the study are duly acknowledged.

Student's Signature: _____ Date: _____

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Acronyms

AFD	Administrative and Finance Division.
AMA	American Medical Association.
DLO	Dzongkhag Livestock Officer.
DOL	Department of Livestock.
DRA	Drug Regulatory Authority.
DVEU	Drugs Vaccines and Equipment Unit.
DVH	Dzongkhag Veterinary Hospital.
ELDU	Extra Label Drug Usage.
EVDP	Essential Veterinary Drug Program.
FDA	Food and Drug Administration.
LCS	Livestock Central Store.
LEC	Livestock Extension Center.
MOAF	Ministry of Agriculture and Forest.
NAH	National Animal Hospital.
NCAH	National Centre for Animal Health.
NSB	National Statistics Bureau.
NVDC	National Veterinary Drugs Committee.
OIE	World Organization for Animal Health.
RNR-EC	Renewable Natural Resources- Extension Center.
STG	Standard Treatment Guidelines.
US	United States.
WHO	World Health Organization

Abstract

There is a growing concern with the inappropriate usage of veterinary drugs and its economical impacts globally and the concerns are equally pertinent to Bhutan too. The present study was aimed at the usage and availability of non patent drugs in veterinary practice of Bhutan. Cross sectional study was done based upon stratified sampling of all agencies under the Department of Livestock and was undertaken from December 2015 to March 2016. The overall mean for non-patent drugs based on availability was 9.04 ± 4.07 and the overall mean for non-patent drugs based on usage in the field was 6.69 ± 3.45. The overall mean availability of non-patent drugs and usage in the field were compared using *Z*-Test at 95% confidence level and the result showed that there is a significant difference between the availability and usage of non-patent drugs in the country ($p < 0.05$). When the mean availability and mean usage of non-patent drugs were compared at the regional levels, the result showed a significant difference too ($p < 0.05$). Similarly, the mean availability of non-patent drugs and usage in the field at RNRECs/LECs level showed statistical significance ($p < 0.05$). In contrast, the comparison of mean availability and mean usage of non-patent drugs at DVHs/DLOs and central farms/central agencies' levels showed no significant difference ($p > 0.05$). In conclusion, there was a mis-match in the availability and usage of non-patent drugs in the field at RNRECs/LECs' level and the list of non-patent drugs which are not required for the country based on the findings of this study was discussed.

Key Words: Non-Patent drugs, Veterinary Practice, Usage and Availability.

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CHAPTRE ONE

Introduction

1.1 Background

Bhutan has a total human population of 745,153 (NSB, 2014). Of this, 60.2% of the total population lives in the rural areas and 90% of the rural households rear livestock. (MOAF, 2012). As of 2014, Bhutan has a total of 1.049 million livestock population which comprises of 0.303 million cattle, 0.045 million yak, 0.001 million buffalo, 0.021 million equine, 0.014 million swine, 0.551million poultry, 0.011 million sheep, 0.049 million goat, 0.032 million cats and 0.025 million dogs (MOAF, 2014).

Animal health services in the country are provided through a network of 275 animal health service centers (NSB, 2014). It comprises of 205 Livestock Extension Centers (LEC) or Renewable Natural Resource Extension Centers (RNREC), 20 District Livestock Offices [DLO], 20 District Veterinary Hospitals (DVH), 12 Central Farms and 18 Central Agencies under the Department of Livestock (NSB, 2014). The animal health services are provided free of cost in the country except for the services provided by the National Animal Hospital [NAH] in Thimphu municipal town [NCAH, 2015].

In order to cater animal health services, various patented and non patent drugs are imported by the country. According to MOAF (2015), The Department of Livestock has a total budget outlay of Nu. 29,000m. for the procurement and distribution of veterinary medicines during the financial year 2015-2016. From this amount Nu. 5.116m (17.64%) was utilized for procuring non-patent drugs in the country, which is comparatively quite high (MOAF, 2015).

The veterinary drugs under the Essential Veterinary Drugs Program [EVDP] comprises of patent and non-patent drugs (MOAF, 2014b). The non-patent drugs include categories of drugs which are herbal, ayurvedic and chemical medicines which are used for treatment of various types of animal health conditions and the Department of Livestock procures 42 kinds of non-patent drugs annually (MOAF, 2014b).

Herbal type of drugs consists of using extracts from plants for the purpose of curing certain deviations from health. They are absolutely natural and devoid of side effects. Usually, herbal medicine is given in the form of extracts and can be continued for life. Herbal medicine can also be given in the form of extracts, tablets, powders, etc. Ayurvedic form of medicine involves the use of tablets made from naturally occurring plants with inclusion of

metals, plants, oils as well as massages and aromatherapy. Ayurvedic system also uses oral syrups for this purpose.

Drugs in animals can be used for various purposes, such as therapeutic, prophylactic (Hirsh and Zee, 1999), growth promotion and other uses (Kanneene *et al.*, 1997). When veterinary drugs are indicated rationally in right dose and route of administration, the potential damages of their use are reduced and their efficacy increased (Vitomir *et al.*, 2011). Rational use of drugs in veterinary medicine has both public health (FAO/OIE/WHO, 2003) and economic significances (WHO, 2001). Non-rational use of drugs in veterinary medicine, as well as the need for control of their use becomes even bigger problem when used on food producing animals (Vitomir *et al.*, 2011).

1.2 Scientific Justifications

The quality of human and veterinary medicines in the country is regulated by the Drug Regulatory Authority [DRA]. This requires the local suppliers for the veterinary medicines to be registered formally with the DRA. However, the implementation of quality control and quality assurance for the veterinary drugs by the DRA and the DOL is inadequate and this problem is greater in case of non-patent drugs, since the drugs are mostly herbal, ayurvedic and chemical drugs. Our country also doesn't have the required drug testing facilities at present.

It has been observed that the local suppliers in the country find it relatively easier to register the non-patent drugs with the DRA compared to patented drugs. Due to this, the accessibility of the non-patent drugs is significantly substantial at the moment in the country. As a result, the clinical efficacy of the non-patent drugs that are being supplied and made available in the field is variable and questionable.

The utilization of non-patent drugs by the LECs, Central Farms and Central Agency is limited since these drugs needs to be compounded or formulated and the knowledge and skills of the para-veterinarians is limited. The non-patent drugs are also used as a placebo treatment in many of the clinical cases of animal diseases by the field staffs and rational utilization of these drugs are questionable.

It has been reported that the expiry of drugs in the country is relatively high and according to the physical verification conducted in the Livestock Central Store [LCS], drugs worth Nu. 1.179 million have expired during the financial year 2012-13 to 2014-15 out of which, 57.42% comprised of non-patent drugs (MOAF, 2015). The report also showed that veterinary medicines worth of Nu. 0.934 million had expired in various parts of the Livestock

Extension Centers in the country during the year 2014-15 with majority of these expired medicines comprised of non-patent drugs (MOAF, 2015).

Limited studies have been done in the country to actually assess the utilization of the non-patent drug in the country. The need to assess the utilization, prioritization and streamlining of procurement and distribution procedures for non-patent drugs had been felt and discussed during the Stakeholders' Meeting on EVDP and the 7th National Veterinary Drug Committee [NVDC] meeting in 2014. Accordingly, this study is proposed to assess the current status of non-patent drugs and their field application in the county and to understand the utilization aspects so that the relevant agency can prioritize and streamline the procurement system.

1.3 Significance of the study

The study on the current status and utilization of non-patent drugs in veterinary practice in the country has never been undertaken till now. The study helped in understanding about the usage, procurement, distribution and management of non-patent drugs in the country under the Essential Veterinary Drug Program. It is providing information about the current issues being faced by the field agencies with regard to procurement, distribution and management of non-patent drugs.

Since the study is the first of its kind, it has provided basic information on the status, importance and utilization of non-patent drugs for veterinary practice in the country. The study is expected to initiate further studies on the use of non-patent drugs and their efficacies in the country. Recommendations based on the research has been submitted to the Department of Livestock and this will aid in streamlining the current procurement, distribution and management of non-patent drugs in the country and also help in rationalization of the use of non-patent drugs in future in the country.

1.4 Aims and Objectives

- Assess the current availability of non-patent drugs in the country
- Assess the usage of non-patent drugs in the country
- Streamline the availability and usage of non patent drugs in veterinary practice in Bhutan

CHAPTER TWO

Literature Review

2. 1 Patent and Non-patent Drugs

Drugs can be categorized in a number of ways in the world of medicine and pharmacology (AMA, 1908). A drug can be classified by its chemical activity or by the condition that it treats (AMA, 1908). However, the concept of patent and non-patent drugs remains important when it comes to prescribing medicines and it is emphasized primarily to reduce the cost of drugs in and around the world [Thakkar *et al.,* 2013].

A patented medicine is a drug to which a patent pertains and provides exclusive rights to the patent holder to use the invention for the duration of the patent (Giorgio *et al.,* 2013). In ancient times, the term "patent" was nostrum remedial "our remedy" in Latin (Oleson, 1896). A patent medicine is a product that is promoted and sold as a medical cure, but that does not provide the promised relief (Shaw, 1972). Patent medicine is a misnomer because, although the product might be trademarked, the patenting process requires proof that the product does something useful (Young, 1961). Patent medicines were one of the first major product categories that the advertising industry promoted, patent medicine promoters pioneered many advertising and sales techniques later used for other products (Shaw, 1972).

When a pharmaceutical company first develops a new drug to be used for a disease condition, it is initially sold under a brand name by which the clinicians can prescribe the drug for use by patients [Giorgio *et al.,* 2013]. The drug is covered under patent protection, which means that only the pharmaceutical company that holds the patent is allowed to manufacture, market the drug and eventually make profit from it (Giorgio *et al.,* 2013).

In most cases, the drug patent is awarded for around twenty years in the United States (Giorgio *et al.,* 2013). The lifetime of the patent varies between countries and also between drugs (Thakkar *et al.,* 2013). Since the company applies for a patent long before the clinical trial to assess a drug's safety and efficacy has commenced, the effective patent period after the drug has finally received approval is often around seven to twelve years (Thakkar *et al.,* 2013).

Once the patent has expired, the drug can be manufactured and sold by other companies (Thakkar *et al.,* 2013). At this point, the drug is referred to as a generic drug (Thakkar *et al.,* 2013). According to guidelines in most countries, including those from the US FDA, generic drugs have to be identical to the branded drug in terms of efficacy, safety, usage, route of drug administration, pharmacokinetics and pharmacodynamics (Thakkar *et al.,* 2013).

A non-patented medicine is a drug that is not protected by a patent, including generic drugs and some brand name drugs (Thakkar *et al.,* 2013). A drug can be manufactured as a non-patent drug when (a) its patent has expired, (b) the company certifies that the patents held on the drug are either unenforceable, are invalid or would not be infringed upon, (c) there has never been any patents on the drug before and (d) in countries where the drug has no patent protection (Thakkar *et al.,* 2013).

Generic drugs are "drugs that are usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights" (Thakkar *et al.,* 2013). When it is said that doctors should prescribe generic drugs, it means that they should prescribe drugs manufactured by other companies after expiry of patent of parent drug of the innovator company (Thakkar *et al.,* 2013). Very often, generic prescribing is misconceived as prescribing by a drug's generic name or non-proprietary name (Thakkar *et al.,* 2013). All generic drugs have a brand name as well as a non-proprietary name but all drugs having a non-proprietary name (generic name) may not be generic drugs (Thakkar *et al.,* 2013).

Non-patent drugs usually require compounding since it involves making a new drug for which safety and efficacy have not been demonstrated with the kind of data that FDA requires to approve a new drug (FDA, 2014). Compounding is any manipulation of a drug beyond what is stipulated on the drug label and it includes mixing, diluting, concentrating, flavoring, or changing a drug's dosage form (FDA, 2014). In virtually all cases, FDA regards compounded medications as unapproved new drugs (FDA, 2014). Thus, compounded medications are considered to be extra label drug use (ELDU) of an approved animal or human drug (FDA, 2014).

The health professionals and consumers can be assured that FDA approved generic drugs have met the same rigid standards as the innovator drug (FDA, 2010). The minimum standards for a generic drug to get FDA approval are (a) contain the same active ingredients as the innovator drug (inactive ingredients may vary), (b) be identical in strength, dosage form, and route of administration, (c) have the same use indications, (d) be bioequivalent, (e) meet the same batch requirements for identity, strength, purity, and quality and (f) be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products (FDA, 2010).

2.2 Significance of non-patent drugs

Creating a drug costs lots of money (FDA, 2010). Since generic drug makers do not developed a drug from scratch, the costs to bring the drug to market are less; therefore, generic drugs are usually less expensive than brand-name drugs (FDA, 2010). But, generic drug makers must show that their product performs in the same way as the brand-name drug (FDA, 2010).

A non-patent or generic drug is identical or "bioequivalent" to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use (FDA, 2010). Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price (FDA, 2010).

Once a non-patent drug is on the market, the monopoly of the patent holder is removed (Thakkar *et al.,* 2013). This encourages competition and results in a significant drop in drug costs, which ensures that life-saving and important drugs reach the general population at comparative prices (Thakkar *et al.,* 2013). The company holding the initial patent may; however, renew the patent by forming a new version of the drug that is significantly changed compared to the original compound (Thakkar *et al.,* 2013). However, this may require new clinical trials and re-application of the patent (Thakkar *et al.,* 2013). Furthermore, the new compound may have to compete with the original generic molecule on the market, unless the drug regulators find faults and remove the original from the market altogether (Thakkar *et al.,* 2013).

2.3 Rational Use of Veterinary Drugs

In simplest words rational use means "prescribing right drug, in adequate dose for the sufficient duration & appropriate to the clinical needs of the patient at lowest cost (Sneha *et al.,* nd). Rational use of drugs in veterinary medicine has numerous benefits, such as increasing efficacy, decreasing the potential adverse effects, reducing risk of drug residue and combating development of microorganism's drug resistance. (Hanmant *et al.,* 2011) Rational use of veterinary drugs means sick animals receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period, and at the lowest cost (Hanmant *et al.,* 2011). On the other hand, irrational use of drug and misuse of drugs by the patient means patients receive medications inappropriate to their clinical needs, under or over dosing, and for inadequate period (Beyene *et al.,* 2014). With the increasing quantity and variety of pharmaceuticals available today in both developed and

developing countries, their potential inappropriate use is a growing concern (Ross-Degnan *et al.,* 1997). Not only the health risks associated with inappropriate drug prescription and usage but also the economic cost to facilities and patients must be considered (Ross-Degnan *et al.,* 1997).

When drugs are used to improve the productivity of food animals that are intended for human consumption, then there is possibility for producing adverse effects on humans (Vitomir *et al.,* 2011). To prevent this risk, it is necessary to use drugs rationally, regularly control sensitivity and also regulate drug agents that are commonly used in veterinary practice (Vitomir *et al.,* 2011).

Irrational use of veterinary medicine as well as the need for control of their use becomes even bigger problem when used on food producing animals (Sanders, 2007). In this case, there is the possibility that minimal quantities of drugs and their metabolites (residues) which remain in edible tissues or in animal products (meat, milk, eggs, honey) induce certain harmful effects in humans as potential consumers of such food (Sanders, 2007). According to Ernest *et al.,* (2005), acquired resistance develops due to widespread and irrational use of drugs while intrinsic resistance is a result of inherent structural or functional characteristics, which allows tolerance of a particular drug. The structured approaches like the standard treatment guidelines (STGs), clinical policies, treatment protocols or best-practice guidelines to diagnosis and therapy have considerable potential to promote rational drug use (Grimshaw *et al.,* 1993).

In 1977, the first WHO Model List of Essential Drugs and Essential Medicines List were published, with the objective to standardize and rationalize treatment, prevent inappropriate use of drugs and facilitate drug procurement and distribution (Everard, 2002). The World Health Organization (WHO) recommends that activities to strengthen the pharmaceutical sector be organized under the umbrella of a national drug policy (WHO, 1988). In many countries, a national essential drugs program is the mechanism for implementing such a policy, usually with emphasis on drug selection, procurement, distribution and use in the veterinary sector (WHO 1988).

2.4 Essential Veterinary Drug Program in Bhutan

The animal health service is provided free of cost through 275 service centers under DOL in the country. One of the important components of services being provided under the animal health program in the country is the procurement, distribution and management of veterinary

drugs, vaccines and equipment under the Essential Veterinary Drug Program (MOAF, 2014c).

The Essential Veterinary Drug Program (EVDP) was created during the early nineties under the European Union supported project "Strengthening of veterinary services for livestock disease control" in Bhutan (MOAF, 2014c). For technical as well as financial viability of EVDP, a seed money of Euro (€) 7,000 was introduced through the project which was operated as revolving fund under Administrative and Finance Division (AFD) of the Ministry of Agriculture and Forests (MOAF) in close liaison with the DOL (MOAF, 2014c). The payment for the supplies was made from the revolving fund account in the AFD under MOAF (MOAF 2014).

However, the system suffered some major constraints resulting in inefficient functioning of the whole EVDP supply chain (MOAF, 2014c). This directly affected the delivery of animal health services at the field level (MOAF, 2014c). With an effort to mitigate the demerits of the then decentralized system, a centralized budgeting was proposed as "Modalities for functioning of centralized budgeting, management, procurement and distribution of veterinary drugs, vaccine and equipment" in 2009, (MOAF 2014c). As per the modalities, funds for medicines, equipments, vaccines are proposed to be centralized with the NCAH from the fiscal year 2009-2010 (MOAF, 2014c). The centralized program was envisioned to operate in the similar line to that of Department of Medical Services of the Ministry of Health (MOAF 2014c). As proposed, a separate Drugs Vaccines and Equipment Unit (DVEU) were created under NCAH for running the proposed arrangement (MOAF 2014c). An improved reporting system of six monthly drug reports was adopted for the purpose of indenting, monitoring and evaluation of the drugs under this system (MOAF 2014c). The National Veterinary Drug Committee (NVDC) was instituted to provide professional input and guide veterinary drugs usage in the country, (MOAF 2014c).

As a part of the EVDP in the country, the DVEU procures a total of 196 medicine items annually out of which 42 are non-patent drugs comprising of 21.9% (NCAH, 2015). The non-patent drugs in Bhutan are those drugs which are generic and include the category of drugs which are herbal, ayurvedic and chemical drugs (MOAF, 2014b). For this, the DVEU spends Nu. 5.116 million (17.64% of the total budget for medicines) to procure non-patent drugs in the country annually (MOAF, 2015). The list of non-patent drugs used in Bhutan under the Essential Veterinary Drug Program is given in annexure 1.

CHAPTER THREE

Materials and Methods

3.1 Study area

The study was conducted throughout the country involving 275 animal health service centre's 205 Livestock Extension Centers (LEC), 20 District Livestock Offices (DLO), 20 District Veterinary Hospitals (DVH), 12 Central Farms and 18 Central Agencies under the Department of Livestock was included.

The study areas are shown in figure 1.

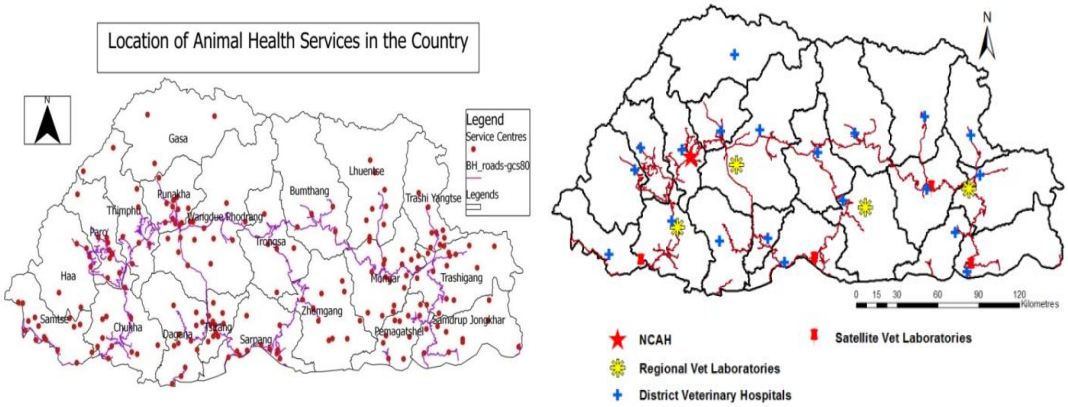

Figure 1.1 Map showing LECs/RNRECs and Farms; **Figure 1.2** Map showing DVHs and Central Agencies

The study was done during the period of November 2015 to June 2016. The actual data collection in the field was done during the period December 2015 to March 2016.

3.2 Study design and sampling

Survey was carried out to assess the usage of non-patent drugs in veterinary practice in Bhutan using a semi-structured questionnaire. The sample size was calculated using WinEpiscope 2.0 version with (95% confidence level and 5% margin of error). A total of 161agencies will involve.

A stratified random sampling and the proportion of sampling method was adopted to select 120 Livestock Extension Centers, 12 District Livestock Offices, 12 District Veterinary Hospitals, 7 Central Farms and 10 Central Agencies under the Department of Livestock.

3.3 Data collection

Data collection was done using semi-structured questionnaire and in specific information on availability of veterinary drugs in the field, types of drugs used were, preferences,

utilization, frequency of use, expiry, problems on use of non-patent drugs, efficacy of non-patent drugs were included. The questionnaire was administered through mail and in some study areas; it was administered by direct approach. A pilot test of all data collection forms, data entry and data analysis was conducted.

3.4 Data analysis

Data was recorded in Microsoft Excel spreadsheet (Version 2007) and imported to PHStat2 was used to analyze the statistical significance of the study results. Means, Median (Range) and Frequencies (Percentage) was used for descriptive statistical analysis.

Mean ranking was used for prioritization, highest as most important and lowest as least important. It was used as a measure for evaluating the process that produces a list of possible responses to a type of drugs and the mean of this are taken for mean ranking.

CHAPTER FOUR

Results and Discussion

4.1 Study respondents and sample characteristics

A total of 137 Agencies responded to the survey out of 161 identified Agencies in the sampling design for the study. Of the total respondents 78.1% were from LECs and RNRECs, 14.6% from DVHs and DLOs, 2.9% from Central Farms and 4.4% are from Central Agencies. The region-wise respondents for the study are given in Table 4.1.

Table 4.1 Region-wise respondents and sample characteristics

Region	Respondents				Total
	LECs/RNRECs	DVHs/DLOs	Central Farms	Central Agencies	
Western	24	5	2	2	33
West Central	26	5	0	1	32
Eastern	42	6	1	2	51
East Central	15	4	1	1	21
Total	107	20	4	6	137

4.2 Categories of veterinary drugs based on availability in the field

The different categories of veterinary drugs based on availability in the field were assessed and the overall mean ranking was highest for antibiotics (11.41 ± 3.25) followed by anthelmentics (10.91 ± 3.80) and minerals/vitamins/infusions fluids (9.11 ± 3.71). The overall mean ranking for drugs based on availability was lowest for life-saving drugs (3.04 ± 2.82) followed by hormones/steroids (4.40 ± 3.18) and anti-fungal drugs (5.09 ± 3.49). The overall mean ranking for non-patent drugs based on availability in the field was 9.04 ± 4.07 (Mean ± SD) and was ranked fourth among the fourteen categories of veterinary drugs.

The mean rankings of veterinary drugs based on availability in the field were compared region-wise and shown in Figure 4.1. The result was similar with the overall means for the highest and lowest ranked categories. However, the non-patent drugs based on availability was ranked fifth in western and eastern regions and third in west central and east central regions.

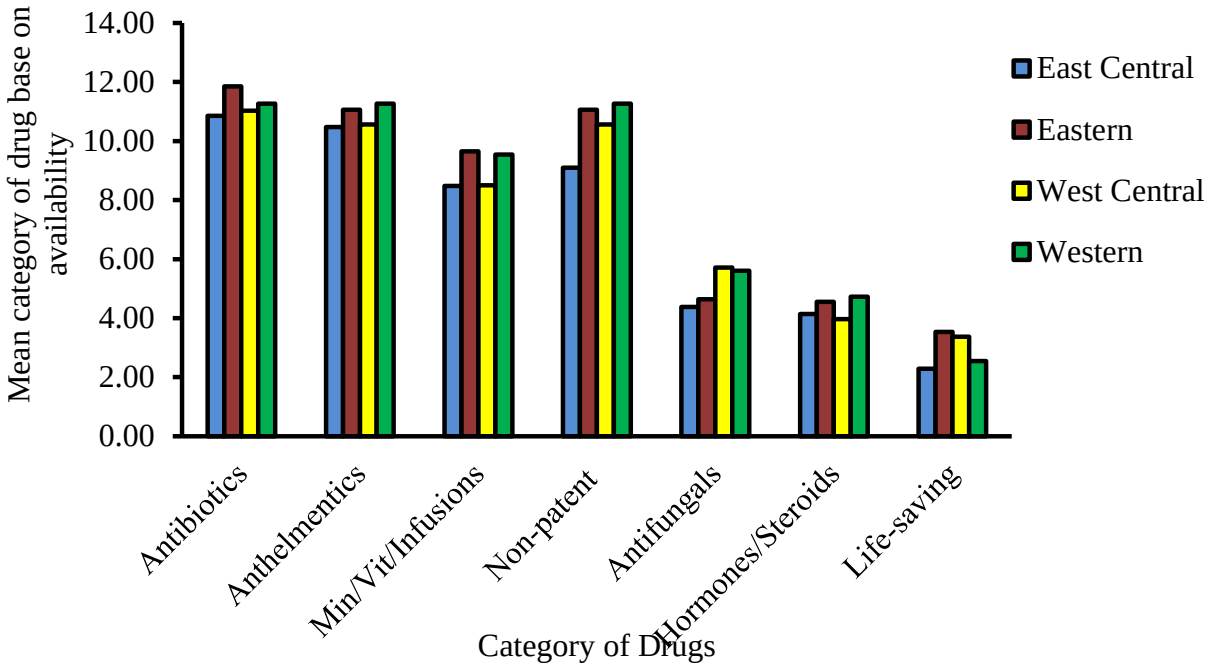

Figure 4.1 Region-wise category of veterinary drugs based on availability

The mean availability of non-patent drugs in the RNRECs/LECs was ranked third whereas the mean availability of non-patent drugs for DVHs/DLOs was ranked eighth and it was ranked fifth for central farms and central agencies. The mean availability of non-patent drugs for RNRECs/LECs was compared with DVHs/DLOs using *t*-Test at 95% confidence level. The result showed that there was a significant difference ($p < 0.05$).

Similarly, the mean availability of non-patent drugs in the RNRECs/LECs was compared with central farms/central agencies using *t*-Test at 95% confidence level. The result showed that there was a significant difference ($p < 0.05$) as given in Table 3.

The mean availability of non-patent drugs in the DVHs/LECs was compared with central farms/central agencies using *t*-Test at 95% confidence level. The result showed that there was no significant difference ($p > 0.05$).

4.3 Categories of veterinary drugs based on usage in the field

The different categories of veterinary drugs based on high usage in the field were assessed for the study. The result showed that the overall mean ranking was highest for antibiotics (11.55 ± 3.26) followed by anthelmentics (10.97 ± 3.38) and minerals/vitamins/infusions fluids (10.18 ± 3.18). The overall mean ranking for drugs based on high usage in the field was lowest for life-saving drugs (3.58 ± 3.09) followed by hormones/steroids (4.24 ± 2.87) and sedatives/tranquilizers/anaesthetics (5.20 ± 3.26). The

overall mean ranking for non-patent drugs based on usage in the field was 6.69 ± 3.45 (Mean ± SD) and was ranked eight among the fourteen categories of veterinary drugs.

The mean rankings of veterinary drugs based on usage in the field were compared region-wise and shown in Table 4.2. The result was similar with the overall means for the highest and lowest ranked categories. However, the non-patent drugs based on usage was ranked tenth for western region, fifth west central region, seventh in eastern region and ninth in east central region.

Table 4.2 Region-wise category veterinary drugs based on usage in the field

Region	Antibiotics	Anthelmentics	Min/Vit/ Infusions	Non-patent	Sed/Tran/ Anesthetics	Hormones /Steroids	Life-saving
East Central	11.90	10.38	9.10	6.62	5.24	4.52	3.52
Eastern	11.61	10.57	10.59	6.92	4.49	4.02	3.24
West Central	10.88	11.84	10.19	6.91	5.66	4.16	4.13
Western	11.88	11.12	10.24	6.18	5.82	4.48	3.64

The mean usage of non-patent drugs in the RNRECs/LECs, DVHs/DLOs and central farms/central agencies were all ranked eighth which was comparable with the overall mean ranking for the usage of non-patent drugs in the country. The mean usage of non-patent drugs for RNRECs/LECs was compared with DVHs/DLOs using *t*-Test at 95% confidence level. The result showed that there was no significant difference ($p > 0.05$).

The mean usage of non-patent drugs for RNRECs/LECs was compared with central farms/central agencies using *t*-Test at 95% confidence level. The result showed that there was no significant difference ($p > 0.05$).

The mean usage of non-patent drugs for DVHs/DLOs was compared with central farms/central agencies using *t*-Test at 95% confidence level. The result showed that there was no significant difference ($p > 0.05$).

4.4 Comparison of non-patent drug availability and usage in the field

The overall mean availability of non-patent drugs and usage in the field were compared using *Z-Test* at 95% confidence level. The result showed that there is significant difference between the availability and usage of non-patent drugs in the country ($p < 0.05$).

The mean availability of non-patent drugs and mean usage of non-patent drugs were compared region-wise and is given in Figure 4.2. The result showed that the availability of non-patent drugs is comparatively higher compared to usage in all the four regions.

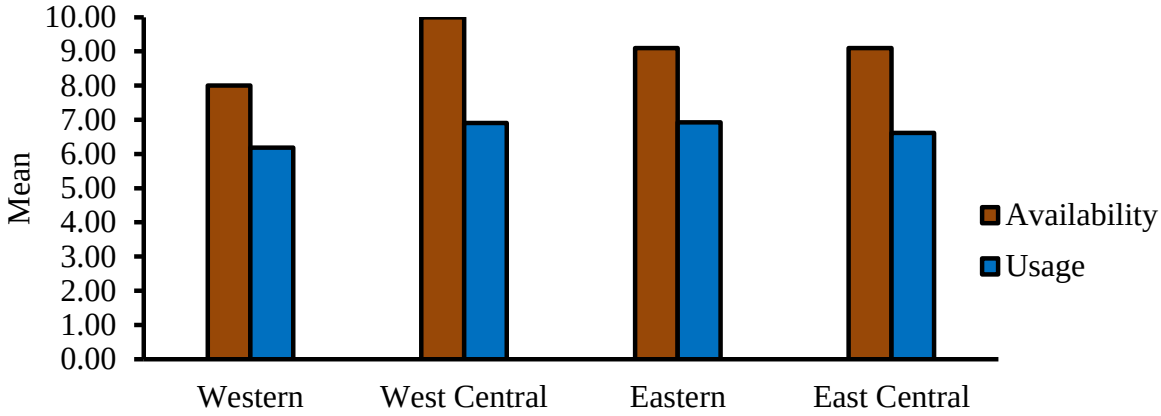

Figure 4.2 Region-wise comparison of availability and usage of non-patent drugs

The mean availability of non-patent drugs and usage in the field at RNRECs/LECs was compared using *Z-Test* at 95% confidence level and the result showed that there was significant difference ($p < 0.05$). In contrast, the mean availability of non-patent drugs and usage for DVHs/DLOs and central farms/central agencies using *t-Test* at 95% confidence level both showed that there were no significant differences ($p > 0.05$). This indicated that the mis-match of availability and usage of non-patent drugs in the field mainly occurred at RNRECs/LECs' level.

4.5 Commonly available categories of non patent drugs

Among the three categories of non-patent drugs available in the country, 8.76% of the respondents reported that herbal drugs are most commonly available non-patent drug category in their centers while 49.64% said it was ayurvedic drugs and 40.15% reported it was chemical drugs. The result was found to be consistent with the distribution of these three categories of non-patent drugs made by NCAH, Serbithang and in line with the available list in the National Veterinary Drug formulary.

4.6 Trends in the requirements and availability of non-patent drugs

The requirement and availability of non-patent drugs in the country was assessed for the last three years, (2013-14, 2014-15 and 2015-16). 60.58% responded that there has not been any change in the requirement and availability. 24.09% reported that it had decreased and the decrease in the trends of requirement and availability of non-patent drugs was mainly attributed to availability of more patented drugs as substitutes at present. On the other hand,

15.33% reported that the trend had increased and the increased trend was attributed mainly because of increase in the commercial farms and more demand for medicines.

The average quantity of non-patent drugs available and maintained in the centers for past three years was evaluated for 42 different types of non-patent drugs in the country. Overall, it was observed that 52.38% of the non-patent drugs fall under 5-10 category followed by 33.33% under < 5 category, 9.52% under 10-15 category and 4.76% under > 15 category.

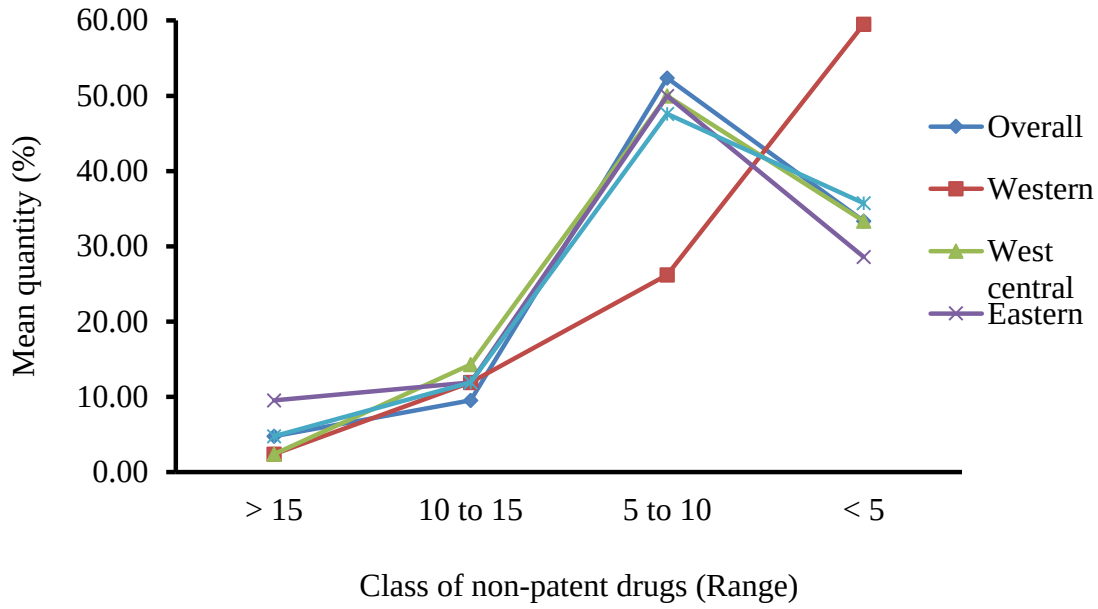

Figure 4.3 Region-wise mean quantity of different types of non-patent drugs

The types of non-patent drugs falling under < 5 category were chloral hydrate, cobalt sulphate, copper sulphate, dicalcium phosphate, ferrous sulphate, light magnesium oxide, potassium iodide, salicyclic acid, sodium chloride, sodium hypochlorite, sodium salicylate, sulphur sublimate, tannic acid and zinc oxide.

Similar trends were observed when compared for the four regions with the exception in western region wherein 59.52% of the non-patent drugs were under < 5 category.

4.7 Satisfaction with the availability of non-patent drugs vis-à-vis essential veterinary drugs

The level of satisfaction with regard to availability of non-patent drugs in the country was compared with the availability of essential drugs and the result is shown in Figure 4.4. The result showed that 80.29% of the respondents were satisfied with the availability of non-patent drugs in the field whereas 76.64% of the respondents were satisfied with the availability of essential veterinary drugs in the country.

The non-satisfaction in the availability of non-patent drugs in the field was mainly attributed to supply of non-patent drugs as a package required for formulation and compounding.

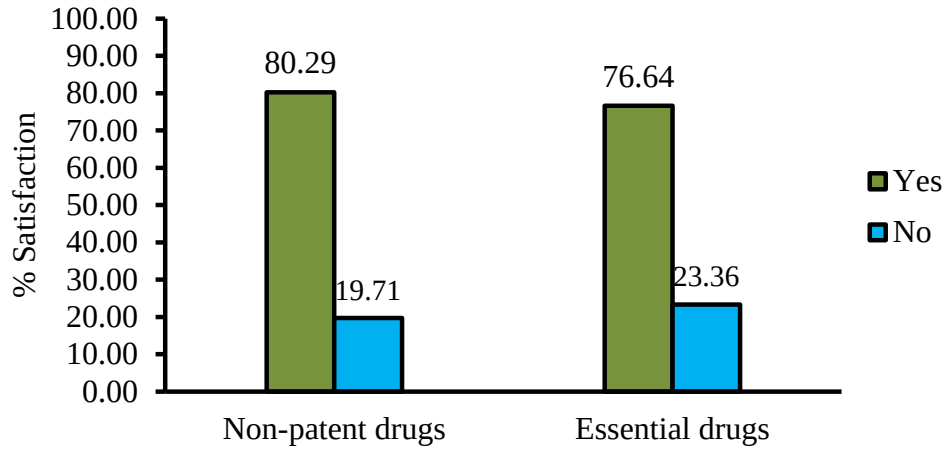

Figure 4.4 Satisfaction in the availability of non-patent drugs and essential veterinary drugs in the country (n=137)

4.8 Usage of non-patent drugs in veterinary practice

The frequency of use of non-patent drugs in the field was assessed and the result is shown in Table 4.3. The result showed that 32.12% use non-patent drugs on a regular basis (daily), 47.45% use intermittently (weekly), 19.71% use rarely (monthly) and 0.73% had never used non-patent drugs in the field.

Out of 44 respondents who reported to use non-patent drugs on a regular basis, 88.64% comprised of RNRECs/LECs followed by 9.09% DVHs/DLOs and 2.27% central farms and central agencies. The result indicates that the use of non-patent drugs is generally common in LECs/RNRECs in the country and it is directly proportional to the level of knowledge and competency that they have with regard to use of non-patent drugs in the field.

Table 4.3 Frequency of use of non-patent drugs in veterinary practice

Frequency of usage	Number of respondents(n)	Percentage of respondents
Regularly	44	32.12
Intermittent	65	47.44
Rarely	27	19.71
Never	1	0.73

The frequency of specific non-patent drugs used in the country was assessed for the 42 different types of non-patent drugs currently available in the national veterinary drug formulary. The result showed that 15 non-patent drugs were occasionally used followed by 14 frequently used, 8 never used and 5 rarely used.

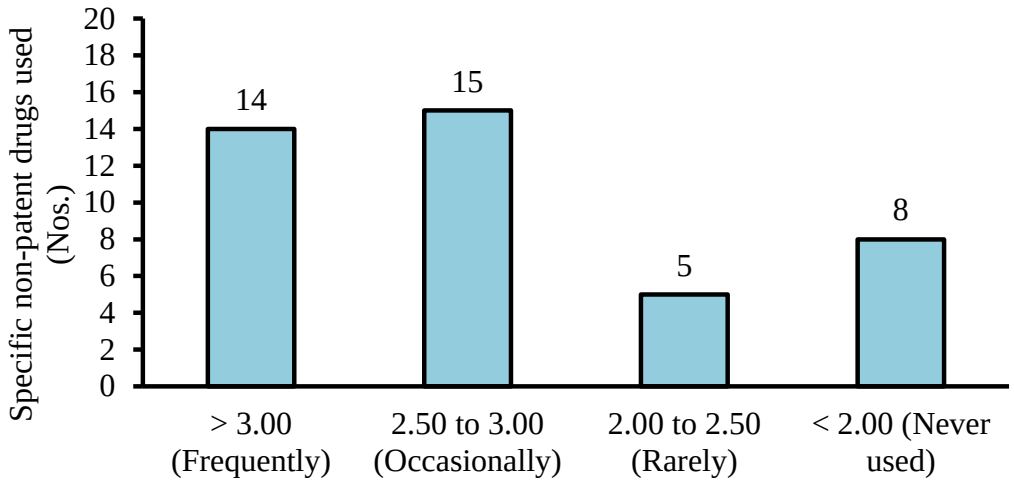

Figure 4.5 Frequency of specific non-patent drugs used in the field

From figure 4.5, the non-patent drugs which are never used were chloral hydrate, cobalt sulphate, copper sulphate, dicalcium phosphate, ferrous sulphate, sodium chloride, sodium hypochlorite and sodium salicylate. The non-patent drugs which were rarely used were alum, potassium iodide, sodium carbonate, sulphur sublime and tannic acid.

Similarly, the most frequently used non-patent drugs in the field were anti-diarrheal powder, anti-cough powder, liver tonic, stomachic powder, anti-bloat powder, uterine tonic powder, turpentine oil, potassium permanganate, tincture iodine, tincture compound benzoin, rectified spirit, hexamine powder, glycerine and boric acid powder.

4.9 Knowledge and confidence in use of non-patent drugs in the field

The level of knowledge assessed with regard to the use of non-patent drugs in the field showed that 52.55% have a good knowledge on the use of non-patent drugs followed by 39.42% fair knowledge and 8.03% poor. 93.46% of the respondents in LECs/RNRECs reported to have fair to good knowledge on the use of non-patent drugs.

The confidence in the use of different categories of veterinary drugs in the field was evaluated and the result showed that the respondents were most confident in using antimicrobial agents with a mean ranking of 5.69 ± 1.78 followed by anthelmentics with a mean of 5.24 ± 1.71 and non-patent drugs with a mean of 4.72 ± 2.19. The respondents were least comfortable in using the life saving drugs with mean ranking of 2.41 ± 1.85 followed by

sedatives/tranquilizers/anesthetics with mean of 2.63 ± 1.70 and hormones/steroids with a mean of 3.08 ± 1.73. The low confidence was because of the fact that life-saving drugs and sedatives/tranquilizers/anesthetics involved risks to patients and hormonal and steroidal drugs required specific diagnostic techniques to support the treatment.

The confidence in the use of different categories of veterinary drugs was compared between the four regions and is shown in Figure 4.6. The result showed that the mean confidence in use of non-patent drugs is ranked third in all the regions. However, the most comfortable drug to be used in the field for western region was anthelmentics with a mean rank of 5.64 ± 1.93 followed by antimicrobial agents (5.39 ± 2.08).

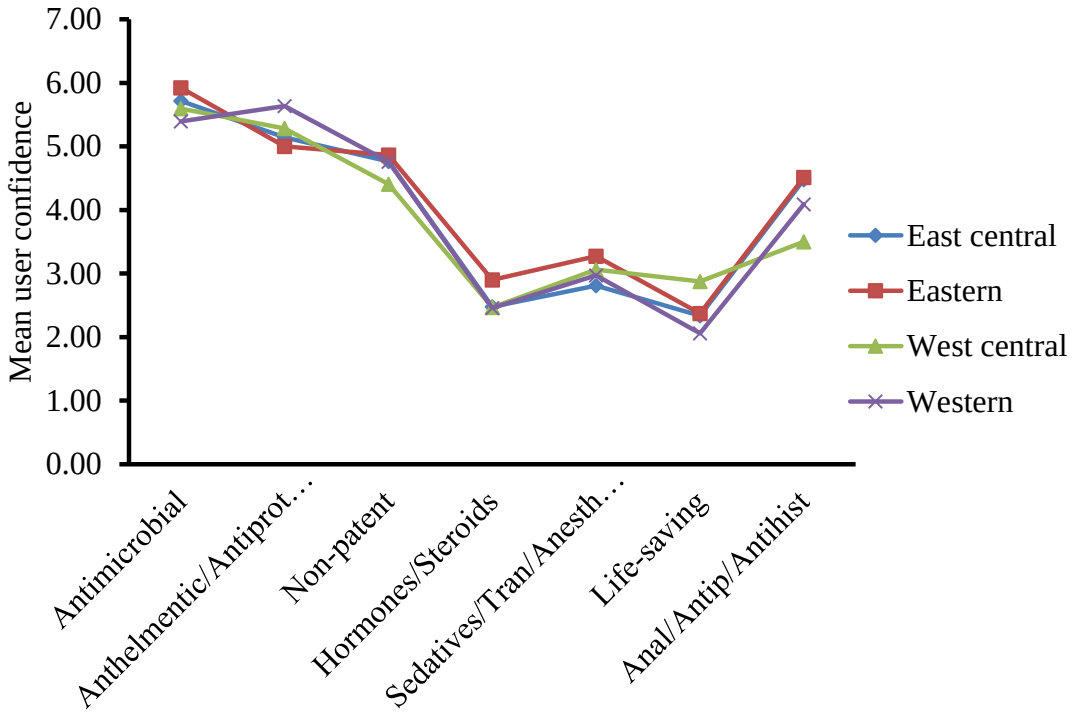

Figure 4.6 Region-wise mean confidence in using veterinary drugs in the field

4.10 Therapeutic importance of non-patent drugs

The observations made from the survey showed that the non-patent drugs were mainly used to treat diseases or conditions like bovine enzootic haematuria, retained placenta, non-specific anorexia, diarrheal conditions and upper respiratory tract infections.

The therapeutic importance of non-patent drugs in the field was assessed and 79.56% of the respondents reported that the non-patent drugs are important in veterinary practice and 8.76% reported that non-patent drugs are not important (Figure 4.7).

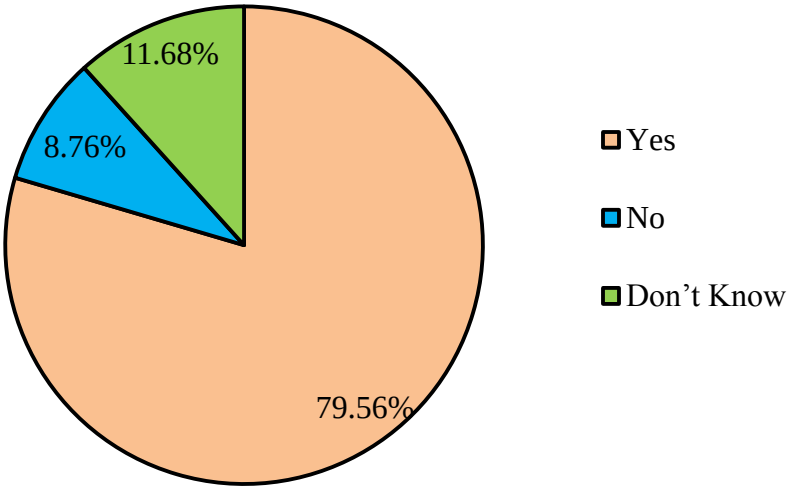

Figure 4.7 Therapeutic importance's of non-patent drugs in veterinary practice

The therapeutic importance of non-patent drugs were compared regionally and 95.24% of the respondents in east central region (n=21) reported it to be important followed by 84.31% in eastern region (n=51), 72.73% in western region (n=32) and 68.75% in west central region (n=33). It indicated that the non-patent drugs are widely used in treatment of livestock diseases in eastern and east central regions compared to western and west central regions. Majority of the respondents felt that the non-patent drugs are important in veterinary practice because they don't have any side effects, are easily available and easy to administer.

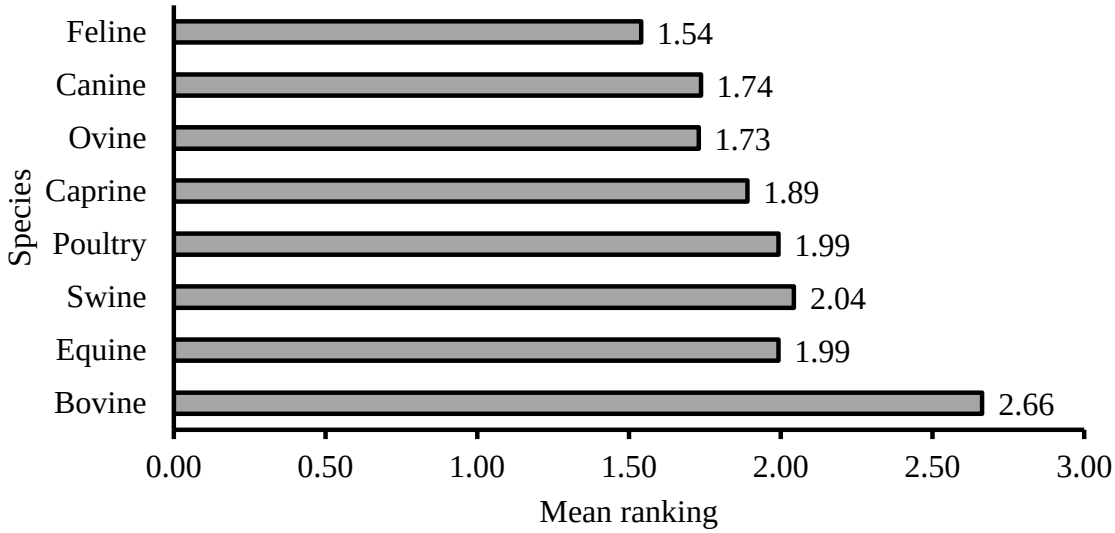

Figure 4.8 Therapeutic importance's of non-patent drugs in different species of animals

The therapeutic importance of non-patent drugs in different species of livestock was evaluated (Figure 4.8). It was found that the non-patent drugs are highly important in bovine with a mean ranking of 2.66 ± 0.56 followed by swine (2.04 ± 0.60) and least important in

feline (1.54 ± 0.59). The main reasons for widely using non-patent drugs in bovine, swine and equine species were because of the fact that non-patent drugs are safe and easy to administer and do not require follow ups like in the case o patented drugs.

4.11 Efficacy of non-patent drugs

The efficacy of non-patent drugs based on the respondents' field experiences was determined during the study. The result showed that 47.41% of the respondents didn't have any idea on the non-patent drugs' efficacy. 26.75% responded that they are highly effective while 21.38% said they are moderately effective and 4.47% responded that the efficacy of the non-patent drugs is low.

The region-wise efficacy of the non-patent drugs was compared and given in Table 4.4. The result showed a similar pattern with the overall efficacy result except for west central region who reported unknown as 42.78% followed by 30.28% moderate efficacy, 19.05% high efficacy and 7.89% low efficacy.

Table 4.4 Region-wise mean and % efficacy of non-patent drugs

Efficacy	East central region (n=21)		Eastern region (n=51)		West central region (n=32)		Western region (n=33)	
	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%	Mean ± SD	%
High	7.95 ± 6.28	37.87	14.79 ± 6.48	28.99	6.10 ± 4.14	19.05	7.81 ± 4.85	23.67
Medium	3.33 ± 2.40	1 5.87	10.21 ± 2.76	20.03	9.69 ± 4.34	30.28	6.05 ± 3.46	18.33
Low	0.50 ± 0.75	2.38	1.86 ± 1.24	3.64	2.52 ±1.70	7.89	1.24 ± 1.23	3.75
Unknown	9.21 ± 6.99	43.88	24.14 ± 6.78	47.34	13.69 ± 5.29	42.78	17.90 ± 6.72	54.26

4.12 Perceptions on substitute drugs for non-patent drugs

The perceptions on the availability of substitute drugs for non-patents drugs in the country were analyzed during the study. Overall, 72.89% of the respondents had no idea on the availability of substitute drugs for non-patent drugs whereas 20.99% of the respondents reported they are aware of the substitute drugs and 6.12% reported that there are no substitute drugs for non-patent drugs. In contrast, it was the central farms and central agencies who had no idea on the availability of substitutes for non-patent drugs (89.76%) followed by DVHs/DLOs (72.14%) and LECs/RNRECs (71.45%).

From the respondents 72.99% reported that they would prefer to use substitute drugs if available instead of non-patent drugs whereas 19.71% reported they do not know and 7.30% said they do not prefer substitute drugs for non-patent drugs.

4.13 Prioritization of non-patent drugs in the field

Out of 42 non-patent drugs available, the result showed that 45.86% of these were essentially required, 38.22% were occasionally required and 15.22% were not required at all. The list of essentially required, occasionally required and not required non-patent drugs as per the respondents' feedback during the study is given in Table 4.5.

Table 4.5 List of required/not required non-patent drugs

Category	Nos. (%)	Name of the non-patent drugs
Essential required	19 (45.86%)	Boric acid, Calcium phosphate, Glycerine, Hexamine, Magnesium sulphate, Potassium permanganate, Rectified spirit, Sodium acid phosphate, Sulphanilamide, Tincture benzoin, Tincture iodine, Turpentine, Anti-bloat, Anti-cough, Anti-diarrheal, Stomachic, Uterine tonic, Liver tonic, Heat inducer
Occasionally required	16 (38.22%)	Alum, Benzoic acid, Dicalcium phosphate, Formaldehyde, Kaolin, Light magnesium oxide, Liquid paraffin, Petroleum jelly, Potassium iodide, Salicylic acid, Sodium bicarbonate, Sodium carbonate, Sulphur sublime, Tannic acid, Zinc oxide, Libido inducer
Not required	7 (15.22%)	Chloral hydrate, Cobalt sulphate, Copper sulphate, Ferrous sulphate, Sodium chloride, Sodium hypochlorite, Sodium salicylate

4.14 Compounding and formulation of non-patent drugs

Among the respondents 68.61% reported that compounding and formulations of non-patent drugs are practiced in the centers whereas 31.39% responded that compounding is not done. The main reasons for not carrying out compounding or formulation were attributed to lack of separate compounding room and facilities. Only 5.11% of the centers have separate compounding room and only 35.04% of the centers reported to have adequate compounding facilities which include prescription balances, spatulas, working bench, packaging materials, mortar and pestle, glass wares and SOPs.

The frequency of compounding done is mostly occasional with 59.85%. 31.39% of the respondents reported that they never compounded while 8.76% reported that compounding is done frequently. When it comes to effectiveness of compounded drugs, 49.63% responded

that compounded drugs were moderately effective, 25.55% highly effective and 24.82% said it was not effective.

The common veterinary formulations done in the centers are given in Figure 4.9. The result showed that antiseptic ointments is the most common compounding done with a mean of 3.81 ± 3.04 followed by urinary antiseptics (3.10 ± 2.87), universal antidotes (2.71 ± 2.64), whitefield's ointment (2.44 ± 2.63), haematinic mixtures (1.87 ± 2.45) and humpsore ointment (1.50 ± 2.35).

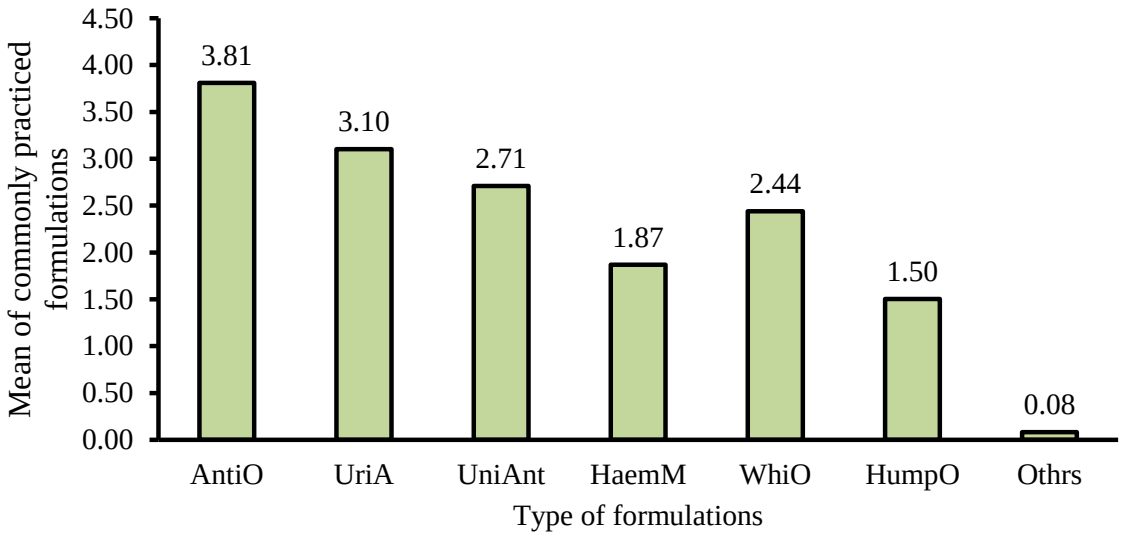

Figure 4.9 Common veterinary formulations/compounding practiced in Bhutan

(AntiO=Antiseptic ointment, UriA+Urinary antiseptics, UniAnt=Universal antidote, HaemM=Haematinic mixture, WhiO=Whitefield's ointment, HumpO=Humpsore ointment)

The knowledge and skills on compounding was assessed and the result showed that the compounding knowledge is only fair in most of the respondents (54.01%) followed by good which comprised of 32.85% and poor which was 13.14%.

4.15 Expiry problems in non-patent drugs

During the assessment of expiry problems in non-patent drugs, 72.99% of the respondents reported that expiry is a major issue in non-patent drugs. The non-patent drugs mostly get expired in the field due to less clinical cases encountered in the field and because of the fact that they have limited applicability in few of the livestock species only. The supply of non-patent drugs in large quantities by NCAH was cited as the third contributing factor for expiry of non-patent drugs.

The expiry of non-patent drugs was compared with other categories of veterinary drugs. Overall, the result showed that sedatives/tranquilizers/anesthetics was expired the most with

mean expiry ranking of 4.19 ± 2.38 followed by non-patent drugs with mean of 3.99 ± 2.56 and hormones/steroids with mean of 3.93 ± 2.40. The region-wise expiry of different categories of veterinary drugs was compared (Figure 4.10) and the result showed the mean expiry was highest in hormones/steroids (4.48 ± 2.44) and the mean expiry in non-patent drugs was ranked fourth (3.57 ± 2.62) in east central region.

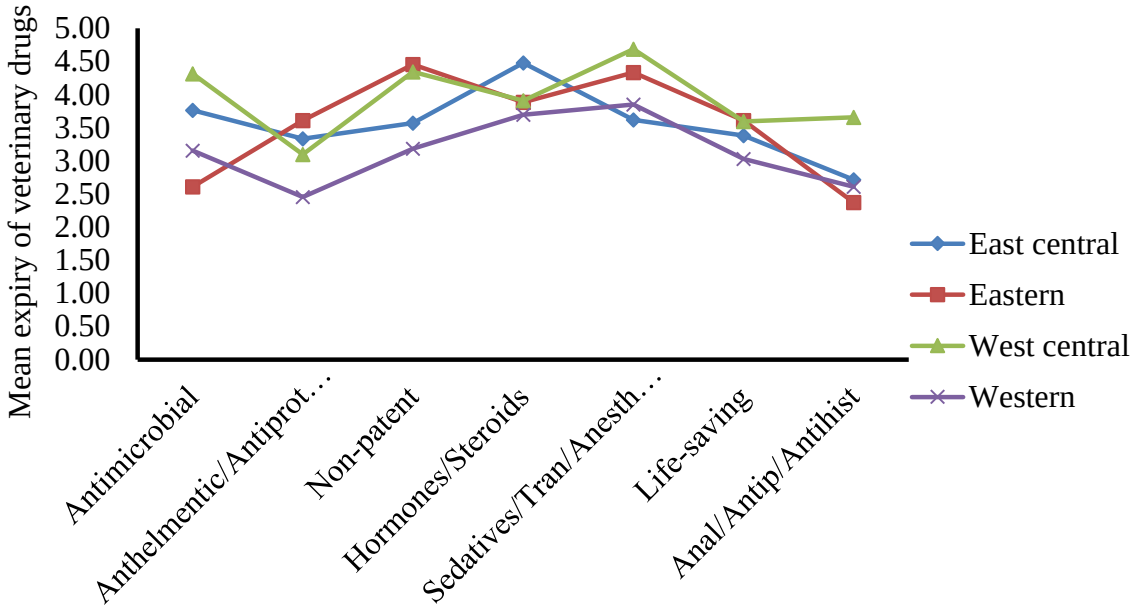

Figure 4.10 Region-wise mean expiry of different categories of veterinary drugs

For eastern region, the mean expiry was highest for non-patent drugs (4.45 ± 2.63). For west central region, the mean expiry was highest in sedatives/tranquilizers/anesthetics (4.69 ± 1.91) and the mean expiry in non-patent drugs was ranked second (4.34 ± 2.12). For western region, the mean expiry was highest for sedatives/tranquilizers/anesthetics (3.85 ± 2.39) and the mean expiry of non-patent drugs was ranked third (3.18 ± 2.69).

The statistical significance of mean expiry of non-patent drugs was compared using *Z*-Test Statistic for differences in two means for all the four regions and the results showed that there were significant difference between eastern and east central region, eastern and western, east central and west central and west central and western regions ($p < 0.05$).

The overall expiry in 42 different types of non-patent drugs available in the country was assessed (Figure 4.11) and the result showed that 66.67% of the non-patent drugs were getting occasionally expired while 16.67% of the non-patent drugs were getting frequently expired. Similarly, 16.67% of the non-patent drugs were getting rarely expired in the field.

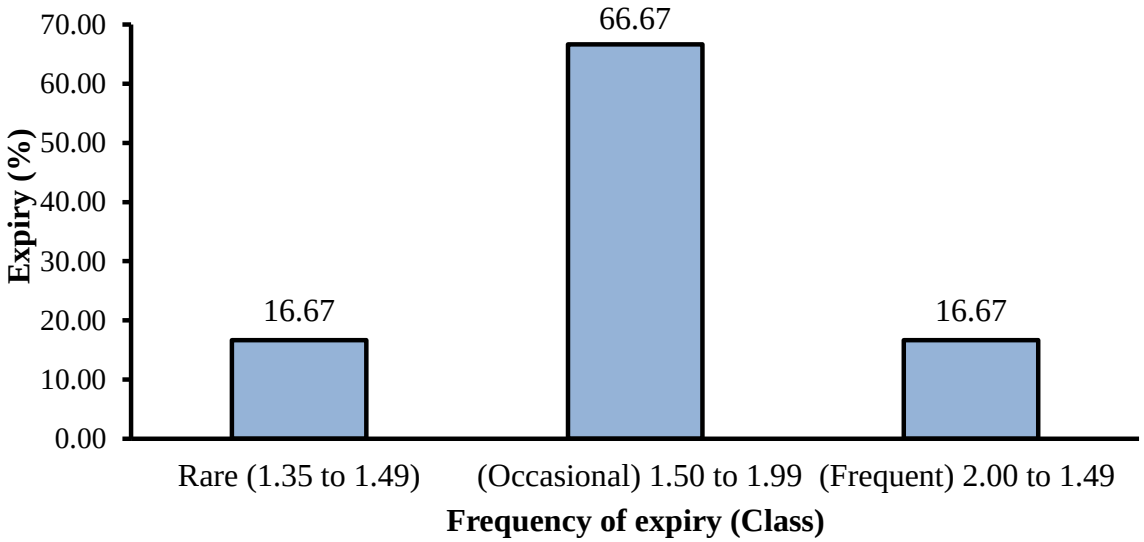

Figure 4.11 Frequency of expiry of non-patent drugs (%)

The different types of non-patent drugs getting frequently expired were alum powder, benzoic acid, chloral hydrate, cobalt sulphate, copper sulphate, ferrous sulphate and sodium salicylate. In contrast, the types of non-patent drugs which were rarely getting expired were glycerin, tincture iodine, turpentine, anti-cough powder, anti-diarrheal powder, stomachic powder and liver tonic powder.

CHAPTER FIVE

5.1 Conclusion and Recommendations

The availability of non-patent drugs and their usage in the field showed that there is a mis-match between the availability and their usage. The differences was mainly found at the LECs and RNRECs levels and was due to the fact that the field requirements and supply were not rationalized based on the therapeutic importance, their efficacy, availability of compounding facilities and the adequate knowledge on their field applicability by the staffs.

The assessment on the types of non-patent drugs required in the field showed that the drugs which were mostly not required were those used in haementic formulations like Cobalt sulphate, Copper sulphate and Ferrous sulphate. Besides, it also included drugs like Chloral hydrate, Sodium chloride, Sodium hypochlorite and Sodium salicylate. These drugs have low applicability or usage in the field. Drugs like Alum, Benzoic acid, Dicalcium phosphate, Formaldehyde, Kaolin, Light magnesium oxide, Liquid paraffin, Petroleum jelly, Potassium iodide, Salicylic acid, Sodium bicarbonate, Sodium carbonate, Sulphur sublime, Tannic acid, Zinc oxide and Libido inducer are occasionally required in the field.

From the point of expiry problems, the different types of non-patent drugs getting frequently expired were Chloral hydrate, Cobalt sulphate, Copper sulphate, ferrous sulphate, Sodium chloride, Sodium hypochlorite, Sodium salicylate.

The study findings recommend the National Centre for Animal Health to rationalize the existing procurement and distribution system for non-patent drugs based on therapeutic importance, usage and efficacy in the country. The relevant agencies should also conduct similar study periodically and update the EVDP list based on field requirements as the requirement and usage of veterinary drugs need to be updated regularly depending on the global advances and scientific breakthroughs.

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Annexure 1 List of Non-Patent Drugs in Bhutan

Sl. No.	Generic Name	Presentation
1	Alum Pure	450 gm pkt.
2	Benzoic acid	450 gm pkt
3	Boric acid	450 gm pkt
4	Charcoal Activated Powder	450 gm pkt
5	Chloral hydrate	450 gm pkt
6	Cobalt sulphate	450 gm pkt
7	Copper sulphate	450 gm pkt
8	Dicalcium phosphate	450 gm pkt
9	Ferrous sulphate	450 gm pkt.
10	Formaldehyde (37-40 %)	500ml bottle
11	Glycerine	350 ml bottle
12	Hexamine	450 gm pkt
13	Kaolin	450 gm pkt
14	Light Magnesium oxide	450 gm pkt
15	Liquid Paraffin	500 ml bottle
16	Magnesium sulphate	450 gm pkt
17	Petroleum jelly	450 gm net
18	Potassium Permanganate	500 gm pkt
19	Potassium iodide	400 gm pkt
20	Rectified Spirit	450 ml bot.
21	Salicylic acid	450 gm pkts
22	Sodium acid phosphate	450 gm pkt
23	Sodium bicarbonate	450 gm pkt
24	Sodium carbonate	450gm pkt
25	Sodium chloride	500gm pkt
26	Sodium hypochlorite	450gm pkt
27	Sodium salicylate	450gm pkt
28	Sulphanilamide	450 ml pkt
29	Sulphur sublimate	450 gm pkt
30	Tannic acid	450gm pkt
31	Tincture Benzoin	450 ml bot.
32	Tincture Iodine	450 ml bottle
33	Turpentine oil	450 ml bottle
34	Zinc oxide	450 gm pkt

Annexure 2 List of Ayurvedic Drugs in Bhutan

Sl. No.	**Generic Name**	**Presentation**
1	Anti-bloat	1 kg pkt.
2	Anti-cough/Expectorant	1 kg pkt.
3	Anti-diarrhoeal	1 kg pkt.
4	Heat inducer	6’s strip cap
5	Libido Inducer	10g X 10 sach. Pkt
6	Livertonic	100 gm X 10 pkt
7	Rumenotoric/Stomachic	1 kg pkt.
8	Spermatogenic	50 g sachet
9	Uterine tonic	1 kg pkt.

Annexure 3 Questionnaire

Assessment of Non-Patent Drug Usage in Veterinary Practice in Bhutan

SELF-ADMINISTERED SURVEY QUESTIONNAIRE

Consent Statement

The information in this schedule has to be collected from the competent/relevant persons working in the Livestock Extension Centers/Renewable Natural Resource-Extension Centers, District Veterinary Hospitals, District Livestock Offices, Central Farms and Central Agencies under the Department of Livestock in Bhutan.

The information you provide will assist in understanding the usage of non-patent drugs in veterinary practice, which will ultimately help in streamlining and strengthening the current procurement, distribution and management of Essential Veterinary Drug Program in the country.

The study is conducted by a student from College of Natural Resources, Lobesa in collaboration with Department of Livestock and will involve many animal health service providers all over the country to make the study fairly representative. The question is to basically ask you about the different aspects of Non-Patent Drugs' usage in the country and we would like to request everyone involved in this study to read the questions carefully, understand and answer honestly based on the current field scenario.

All the responses provided by you will be used for the purpose of research only and the identities of the respondents will be kept confidential.

Name of Respondent: ..... Date of Interview: _____/_____/_____

Type of Respondent: ☐Central Agency ☐Central Farms ☐RLDCs ☐SVLs ☐DVHs ☐ LECs ☐RNRECs ☐ DLOs

Name & Location of CA/CF/RLDC/SVL/DVH/LEC/RNREC/DLO:

……

Dzongkhag: …… Region: …….

Part II Current Status and Indenting of Non-Patent Drugs

2.1. Rank the following categories of veterinary drugs based on availability in high quantities as per your annual indents in your centre/agency *(Ranking must be from top to bottom on a scale of 1 to 14; wherein 1 is the highest and 14 is the lowest)*

Antibiotics □ Anthelmentics □ External parasiticides □
Anti-fungals □ Anti-protozoals □ Minerals,Vitamins and Infusions □
Non-patent drugs □ External parasiticides □ Hormones and Steroids □
I/mammary and I/uterine Infusions Drugs □Sedatives/Tranquilizers/Anaesthetics
Analgesics/Anti-pyretics/Anti-histaminics □ Life-saving Drugs □
External Ointments and Sprays including Eye/Ear Ointments □

(Note: Life-saving drugs include categories like diuretics, anti-convulsants, emetics and anti-emetics, cardiac and respiratory stimulants, haemostatic drugs, anti-neoplastics, anti-dotes, etc)

2.2. Rank the following categories of various veterinary drugs based on high usage in the field of veterinary practice in Bhutan *(Ranking must be from top to bottom on a scale of 1 to 14; wherein 1 is the highest rank and 14 is the lowest)*

Antibiotics □ Anthelmentics □ External parasiticides □
Anti-fungals □ Anti-protozoals □ Minerals,Vitamins and Infusions □
Non-patent drugs □ External parasiticides □ Hormones and Steroids □
I/mammary and I/uterine Infusions Drugs □Sedatives/Tranquilizers/Anaesthetics
Analgesics/Anti-pyretics/Anti-histaminics □ Life-saving Drugs □
External Ointments and Sprays including Eye/Ear Ointments □

2.3. Which are the most commonly available categories of non-patent drugs in your centre/agency? (Rank from top to bottom on a scale of 1 to 3)

Herbal drugs □ Ayurvedic drugs □ Chemical drugs □

2.4. Do you think the requirements and availability of non-patent drugs had increased or decreased during the last 3 years? Increased □ Decreased □ No change in the trend □

2.4.1. If increased, give 2 main reasons for the increasing trend

□ ……
□ ……
□ ……
□ ……

2.4.2. If decreased, give 2 main reasons for the decreasing trend

□ ……
□ ……
□ ……
□ ……

2.5. How satisfied are you with regard to availability of non-patent drugs in your centre/agency?

□ Yes □ No

2.5.1. If "No," give reasons for the low level of satisfaction.

□ ……

2.6. How satisfied are with regard to availability of essential veterinary drugs in your centre/agency? □ Yes □ No

2.6.1. If "No," give reasons for the low level of satisfaction.

□ ……

□ ……

2.7. What is the average quantity (In Numbers) of non-patent drugs that you usually keep in your centre/agency? ***(Please consider average for 3 years i.e. 2015-16, 2014-15 and 2013-14)***

Generic Name	Unit	Average Qty	Generic Name	Unit	Average Qty
Alum Pure powder	Pkt		Sodium acid phosphate pdr	Pkt	
Benzoic acid powder	Pkt		Sodium bicarbonate pdr	Pkt	
Boric acid powder	Pkt		Sodium carbonate pdr	Pkt	
Charcoal Activated powder	Jar		Sodium chloride pdr	Pkt	
Chloral hydrate powder	Pkt		Sodium hypochlorite pdr	Pkt	
Cobalt sulphate powder	Pkt		Sodium salicylate powder	Pkt	
Copper sulphate powder	Pkt		Sulphanilamide powder	Pkt	
Dicalcium phosphate pdr	Pkt		Sulphur sublimate pdr	Pkt	
Ferrous sulphate powder	Pkt		Tannic acid powder	Pkt	
Formaldehyde	Bot		Tincture Benzoin	Bot	
Glycerine	Bot		Tincture Iodine	Bot	
Hexamine powder	Pkt		Turpentine oil	Bot	
Kaolin powder	Pkt		Zinc oxide powder	Pkt	
Light magnesium oxide pdr	Pkt		Anti-bloat powder	Pkt	
Liquid Paraffin	Bot		Anti-cough powder	Pkt	
Magnesium sulphate pdr	Pkt		Anti-diarrheal powder	Pkt	
Petroleum jelly	Jar		Stomachic powder	Pkt	
Potassium Permanganate	Pkt		Uterine tonic powder	Pkt	
Potassium iodide	Pkt		Livertonic powder	Pkt	
Rectified Spirit	Bot		Heat inducer tablet	Strip	
Salicylic acid powder	Pkt		Libido inducer powder	Pkt	

Part III. Current Usage of Non-Patent Drugs

3.1. How commonly do you use non-patent drugs in your centre/agency?

□ Regularly (Daily) □ Intermittently (Weekly)
□ Rarely (Monthly) □ Never

3.1.1. If they are used, what are some of the commonest conditions/diseases that they are used for in your centre/agency? *(Please mention the top 5 common conditions/diseases ranking from top to bottom)*

1…….2)……

3)……..4)…….

3.2. What is your level of knowledge with regard to use of non-patent drugs in the field?

□ Good □ Fair □ Poor

3.2.1. If "Poor," give reasons.

□ ……
□ ……

3.2.2. Among the following categories of veterinary drugs, which do you feel comfortable in using them during your daily practice? *(Rank them from top to bottom on a scale of 1 to 7, wherein 1 is most comfortable and 7 is least comfortable)*

Antibiotics □ Anthelmentics □ External parasiticides □
Anti-fungals □ Anti-protozoals □ Minerals,Vitamins and Infusions □
Non-patent drugs □ External parasiticides □ Hormones and Steroids □
I/mammary and I/uterine Infusions Drugs □Sedatives/Tranquilizers/Anaesthetics
Analgesics/Anti-pyretics/Anti-histaminics □ Life-saving Drugs □
External Ointments and Sprays including Eye/Ear Ointments □

3.2.3. If the ranking is 6 or 7 in the above, give reasons for the low level of comfort in using this particular category of veterinary drugs.

□ ……
□ ……
□ ……
□ ……

3.3. Do you think non-patent drugs are highly important for therapeutic use in veterinary practice?

□ Yes □ No □ Don't Know

3.3.1. If yes, why do you think non-patent drugs are so important in veterinary practice? (Please tick whichever is relevant)

□ They are effective against several conditions/diseases in animals
□ They are not effective but can be used as placebo & to maintain Public Relation with farmers
□ They are commonly available in the market and easy to dispense/administer
□ There are no substitutes for these drugs from the patented drug list in the country
□ They don't have any side effects
□ Others (Specify): …….

3.4. How frequently do you use these specific non-patent drugs by your centre/agency? ***(Please complete the following table indicating your answer with a (✓) mark wherever relevant)***

Sl. No.	Generic Name	Frequency of use in the field			
		Never	**Rarely**	**Occasionally**	**Frequently**
1	Alum pure powder				
2	Benzoic acid powder				
3	Boric acid powder				
4	Charcoal activated powder				
5	Chloral hydrate powder				
6	Cobalt sulphate powder				
7	Copper sulphate powder				
8	Dicalcium phosphate pdr				
9	Ferrous sulphate powder				
10	Formaldehyde solution				
11	Glycerine suspension				
12	Hexamine powder				
13	Kaolin powder				
14	Light magnesium oxide pdr				
15	Liquid Paraffin solution				
16	Magnesium sulphate pdr				
17	Petroleum jelly				
18	Potassium permanganate				
19	Potassium iodide				
20	Rectified spirit				
21	Salicylic acid powder				
22	Sodium acid phosphate pdr				
23	Sodium bicarbonate pdr				
24	Sodium carbonate pdr				
25	Sodium chloride pdr				
26	Sodium hypochlorite pdr				
27	Sodium salicylate powder				
28	Sulphanilamide powder				
29	Sulphur sublimate pdr				
30	Tannic acid powder				
31	Tincture benzoin coumpound				
32	Tincture iodine solution				
33	Turpentine oil				
34	Zinc oxide powder				
35	Anti-bloat powder				
36	Anti-cough powder				
37	Anti-diarrheal powder				
38	Stomachic powder				
39	Uterine tonic powder				
40	Liver tonic powder				
41	Heat inducer tablet				
42	Libido inducer powder				

3.5. Indicate a specific condition/disease that you use each of the non-patent drugs listed below with its efficacy level and availability of substitutes from the patented drug list in the country.

Sl. No.	Generic Name	Disease/Condition	Efficacy (High/Medium/Low)	Substitute (Yes/No/No Idea)
1	Alum pure powder			
2	Benzoic acid powder			
3	Boric acid powder			
4	Charcoal activated powder			
5	Chloral hydrate powder			
6	Cobalt sulphate powder			
7	Copper sulphate powder			
8	Dicalcium phosphate pdr			
9	Ferrous sulphate powder			
10	Formaldehyde solution			
11	Glycerine suspension			
12	Hexamine powder			
13	Kaolin powder			
14	Light magnesium oxide pdr			
15	Liquid Paraffin solution			
16	Magnesium sulphate pdr			
17	Petroleum jelly			
18	Potassium permanganate			
19	Potassium iodide			
20	Rectified spirit			
21	Salicylic acid powder			
22	Sodium acid phosphate pdr			
23	Sodium bicarbonate pdr			
24	Sodium carbonate pdr			
25	Sodium chloride pdr			
26	Sodium hypochlorite pdr			
27	Sodium salicylate powder			
28	Sulphanilamide powder			
29	Sulphur sublimate pdr			
30	Tannic acid powder			
31	Tincture benzoin compound			
32	Tincture iodine solution			
33	Turpentine oil			
34	Zinc oxide powder			
35	Anti-bloat powder			
36	Kaflon powder			
37	Neblon powder			
38	Digestovet powder			
39	Utrona powder			
40	Liver tonic powder			
41	Prajana/Sajana tablet			
42	Tentex forte/Spemen pdr			

(In the Disease/Condition column, write as "UK" if you don't know which condition/disease the drug is used)

3.6. If substitutes are available in the form of patented drugs for these non-patent drugs, would you prefer to use the patented substitute drugs?

□ Yes □ No □ Don't know

3.6.1. If "no," give reasons why you cannot use patented drug substitutes for non-patent drugs?

□ ……

□ ……

3.7. How important are the non-patent drugs for therapeutic use in the following species of animals? ***(Please complete the table indicating your answer with a (✓) mark wherever relevant)***

Species of Animal	Not Important	Moderately Important	Highly Important
Bovine			
Equine			
Swine			
Poultry			
Caprine			
Ovine			
Canine			
Feline			

3.7.1. Give reasons why non-patent drugs are important in certain species of animals that you indicated in table 3.7 above.

□ ……

□ ……

3.8. Is there any "NEW" non-patent drugs that you think needs to be included in the Veterinary Drug Formulary and EVD List of Bhutan?

□ Yes □ No

3.8.1. If "yes," mention the name and type of new non-patent drugs to be included in the Drug Formulary and EVD List 2015.

Generic/Trade Name	Strength/Composition	Presentation	Manufacturer

3.9. Prioritize the following non-patent drugs as "ER – Essentially required," "OR – Occasionally required," and "NR – Not required" depending on their importance, usage and availability of substitutes so that the non-patent drugs can be retained/deleted during the review of the existing Drug Formulary and EVD List.

Generic Name	ER/OR/NR	Generic Name	ER/OR/NR
Alum Pure powder		Sodium acid phosphate pdr	
Benzoic acid powder		Sodium bicarbonate pdr	
Boric acid powder		Sodium carbonate pdr	
Charcoal Activated powder		Sodium chloride pdr	
Chloral hydrate powder		Sodium hypochlorite pdr	
Cobalt sulphate powder		Sodium salicylate powder	
Copper sulphate powder		Sulphanilamide powder	
Dicalcium phosphate pdr		Sulphur sublimate pdr	
Ferrous sulphate powder		Tannic acid powder	
Formaldehyde		Tincture Benzoin	
Glycerine		Tincture Iodine	
Hexamine powder		Turpentine oil	
Kaolin powder		Zinc oxide powder	
Light magnesium oxide pdr		Anti-bloat powder	
Liquid Paraffin		Anti-cough powder	
Magnesium sulphate pdr		Anti-diarrheal powder	
Petroleum jelly		Stomachic powder	
Potassium Permanganate		Uterine tonic powder	
Potassium iodide		Livertonic powder	
Rectified Spirit		Heat inducer tablet	
Salicylic acid powder		Libido inducer powder	

3.10. What are some of the major constraints in using non-patent drugs in the field by your centre/agency?

□

…….

□

…….

Part IV. Compounding and Formulations of Non-Patent Drugs

4.1. Do you compound and formulate veterinary drugs using non-patent drugs in your centre/agency? □ Yes □ No (If no, go to question 4.6.)

4.1.1. If "yes," how frequently do you compound and formulate the drugs?

□ Frequently □ Occasionally □ Never

4.2. What is the efficacy of the compounded/formulated drugs that you have observed in the field when used by your centre/agency?

□ Highly effective □ Moderately effective □ Not effective

4.3. What type of compounding area do you have in your centre/agency at present? ***(Tick whichever is relevant)***

□ Separate room for compounding
□ Compounding within dispensary room
□ Compounding room combined with office

4.3.1. What types of compounding equipments/materials do you have in your centre/agency? ***(Mark as Yes/No whichever is relevant)***

Compounding equipments/materials	Present (Yes/No)	Quantity (Nos.)
Prescription balances/electronic balances		
Spatulas		
Working bench/slabs for making ointments/powders, etc		
Packaging materials		
Glass wares (Conical flasks, measuring jars, pipettes, etc)		
Mortar and Pestle		
SOPs and Guidelines for compounding/formulations		

4.4. What types of veterinary drug formulations do you commonly practice and for which conditions are they used in your centre/agency? ***(Tick the most relevant ones for your centre/agency and rank them from top to bottom on a scale of 1 to 7).***

Sl. No.	Name of Formulary	Tick (✓)	Ranking	Condition/Disease Used
1	Antiseptic ointments			
2	Urinary antiseptics			
3	Universal Antidotes			
4	Haematinic mixtures			
5	Whitefield's ointment			
6	Humpsore ointment			
7	Others(Specify)			

4.5. What is the frequency of compounding/formulation practiced by your centre/agency? ***(Tick the most relevant ones in the table below).***

Name of Formulary	Frequency of Compounding/Formulation			
	Never	Rarely	Occasionally	Frequently
Antiseptic ointments				
Urinary antiseptics				
Universal Antidotes				
Haematinic mixtures				
Whitefield's ointment				
Humpsore ointment				
Others (Specify)				

4.6. What is your level of knowledge and skills with regard to compounding and formulation of non-patent drugs?

□ Good □ Fair □ Poor

4.6.1. If "Poor," give 2 reasons for the low level of expertise in compounding and formulation of non-patent drugs.

□ ……

□ ……

Part V. Expiry Problems in Non-Patent Drugs

5.1. Do you experience expiry problems for non-patent drugs in your centre/agency?

□ Yes □ No □ Not observed

5.2. What are the major reasons for expiry of non-patent drugs in your centre/agency? (Tick whichever is appropriate and also rank from top to bottom on a scale of 1 to 5)

□ Non-patent drugs are supplied with shorter shelf life
□ Non-patent drugs are supplied in large quantities by DVEU/LCS (Not as per indent)
□ Only few clinical cases are encountered in the field which requires treatment using non-patent drugs
□ Limited use due to their limited applicability in few species of animals
□ Others (Specify): ……

5.3. Among the following categories of veterinary drugs, which gets expired more frequently in your centre/agency? ***(Rank them from top to bottom on a scale of 1 to 7)***

Anti-microbial Agents □ Anthelmentics/Anti-protozoals Drugs □
Non-patent drugs □ Hormones and Steroids
Sedatives/Tranquilizers/Anaesthetics □Life-saving Drugs □
Analgesic/Anti-pyretic/Anti-histaminic Drugs □

5.4.How do you dispose the expired Drugs?

Direct incineration □ Directly into disposal pit □
Facilitated through RLDCs/NCAH □ Direct dumping in LCS □ No disposal mechanism in place □

5.5.What are the difficulties that you face in disposal of these expired non-patent drugs?

□…….
□…….
□…….
□…….

5.6.*Among the various non-patent drugs, how frequently do they get expired in the field?** ***(Please complete the following table indicating your answer with a* (✓) *mark wherever relevant

Sl. No.	Generic Name	Frequency of Expiry in the Field			
		Never	**Rarely**	**Occasionally**	**Frequently**
1	Alum pure powder				
2	Benzoic acid powder				
3	Boric acid powder				
4	Charcoal activated powder				
5	Chloral hydrate powder				
6	Cobalt sulphate powder				
7	Copper sulphate powder				
8	Dicalcium phosphate pdr				
9	Ferrous sulphate powder				
10	Formaldehyde solution				
11	Glycerine suspension				
12	Hexamine powder				
13	Kaolin powder				
14	Light magnesium oxide pdr				
15	Liquid Paraffin solution				
16	Magnesium sulphate pdr				
17	Petroleum jelly				
18	Potassium permanganate				
19	Potassium iodide				
20	Rectified spirit				
21	Salicylic acid powder				
22	Sodium acid phosphate pdr				
23	Sodium bicarbonate pdr				
24	Sodium carbonate pdr				
25	Sodium chloride pdr				
26	Sodium hypochlorite pdr				
27	Sodium salicylate powder				
28	Sulphanilamide powder				
29	Sulphur sublimate pdr				
30	Tannic acid powder				
31	Tincture benzoin				
32	Tincture iodine solution				
33	Turpentine oil				
34	Zinc oxide powder				
35	Anti-bloat powder				
36	Anti-cough powder				
37	Anti-diarrheal powder				
38	Stomachic powder				
39	Uterine tonic powder				
40	Liver tonic powder				
41	Heat inducer tablet				
42	Libido inducer powder				

(THANK YOU FOR YOUR VALUABLE TIME)

Annexure 4 Budget Proposal for Study on Non-patent Drug Usage in Veterinary Practice in Bhutan

Sl. no	**Activities/Particulars**	**Unit**	**Quantity**	**Rate**	**Amount**	**Remarks**
1	DA claim for 15 days @ Nu. 750 for Data collection	Days	90 (4months)	750	67,500	
2	Purchase of photocopy paper	Rims	4 (Nos.)	200	800	
3	Purchase of Gsm paper	Rims	1 (Nos.)	800	800	Final Printing
4	Printing Charge for Questionnaires	Per Page	161sets X 10 pages (1610 pages)	5	8050	
5	Dissertation binding Charge	Nos.	3 (Nos.)	1000	3000	
6	Miscellaneous				5000	
TOTAL					**85,150 (Eighty Five thousand one hundred fifty) only**	

Annexure 5 Dissertation work plan (2015-2016)

	Activities	Months								Remarks
		N	D	J	F	M	A	M	J	
1	Submission of Project Proposal									20th November, 2016
2	Evaluation of project proposal									8th December, 2016
3	Data Collection									
4	Progress report & consultation									15th February, 2016
5	Progress report & consultation									15th March, 2016
6	Report writing, data analysis and compilation									
7	Submission of 1st draft									22nd April 2016
8	Submission of 2nd draft									13th May 2016
9	Article draft submission									1st June 2016
10	Oral presentation									13th June 2016
11	Final submission to the college									27th June 2016

Project supervisor: Dr. Tshering Gyeltshen Signature:

Date: 23/10/2015

Project Author: Sonam Rinchen Signature:

Date: 23/10/2015