NATIONAL DRUG AUTHORITY

DRUG INFORMATION DEPARTMENT

REPORT ON INVESTIGATIONS ON USE OF ARVS IN PIGS IN OYAM DISTRICT OF NORTHERN UGANDA



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TABLE OF CONTENTS

COVER PAGE	i
TABLE OF CONTENTS	ii
ABBREVIATIONS AND ACRONYMS	iii
1. INTRODUCTION	1
1.1 Back ground	1
1.2 Objectives	1
2.0 LITERATURE REVIEW	2
2.1 Pig farming in Uganda	2
2.2 HIV Infection rates in Uganda	2
2.3 Mechanism of action of ARVs	2
2.4 Fat redistribution properties of ARVs	3
2.5 African Swine Fever	3
3.0 METHODS AND MATERIALS	4
3.1 Study area – Oyam District of Northern Uganda	4
4.0 RESULTS	5
4.1 Use of ARVs in animals	5
4.2 Source of ARVs used to treat animals	6
4.3 Community perception of the problem and factors leading to the practice	7
4.4 Other human drugs used in livestock and their indications	8
5.0 DISCUSSION	9
6.0 CONCLUSIONS AND RECOMMENDATIONS	11
6.1. Conclusion	11
6.2. Recommendation	11
6.3 Limitations	11
7 O REFERENCES	12

ABBREVIATIONS AND ACRONYMS

AIDS Acquired Immuno Deficiency Syndrome

ART Anti-Retroviral Therapy

ARVs Anti-Retroviral Drugs

ASF African Swine Fever

DHO District Health Officer

DVO District Veterinary Officer

FDC Fixed Dose Combination

HIV Human Immunodeficiency Virus

NCD New Castle Disease

NDA National Drug Authority

NRTI Nucleoside (analogue) Reverse Transcriptase Inhibitor

NNRTI Non-Nucleoside (analogue) Reverse transcriptase Inhibitor

UAIS Uganda AIDS Indicator Survey

PI Protease Inhibitors

HBV Hepatitis B Virus

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National Drug Authority and National Pharmacovigilance Center in particular would like to commend the increasing level of awareness about rational use of drugs in the communities. It is because of the increased vigilance that such practices as abuse of ARVs have come to light and this gives us an opportunity for early detection and action. We thank the administration of Oyam District especially Dr. Ogwal Tom (DVO) and his veterinary team, Ms Agaro Caroline (Acting DHO) and her team, Dr. Opira Wilfred, farmer groups of Iceme Subcounty, and all those who have assisted in one way or the other to come up with this report. Together we shall achieve.

1. INTRODUCTION

Extra-label use of drugs has always been a common practice in veterinary medicine owing to the lack of equivalent preparations of certain drugs for veterinary practice. It has also been reported as a common practice among farmers due to self medication. In absence of regulation, farmers can try out anything to reduce cost of production and save the lives of their livestock against the food safety objectives. Use of veterinary drugs for treatment of humans has also been identified as a common practice.

In September 2013, *The Daily Monitor* one of the Ugandan daily news papers published an article where farmers in Oyam District were reported to be using ARVs to fatten pigs.

Apart from the fattening objective probably due to the fat redistribution properties of some ARVs (Nolan, et al., 2005), it was found out that farmers are experimenting the anti-viral properties of ARVs to control and treat *African swine fever* a disease of pigs that has had a big impact on the pig industry in Northern Uganda, among other diseases of livestock. This issue also attracted a lot of debate in professional forums e.g. the Ugandan Veterinary Forum. This is a classical example of irrational use of drugs which can have far reaching consequences on public health and on HIV/AIDS programs in the country.

Despite these reports, there has been paucity of information about their authenticity and to support course of action in order to mitigate the problem.

A study was been instituted by the National Drug Authority (NDA) to investigate the authenticity of these reports and thereby recommend actions to address the problem.

The study focused on the following objectives:

- To establish the authenticity of the reports of use of ARVs in pigs in Oyam District
- ii. To assess the factors in the area leading to the practice and modes of acquisition of the ARVs for use in animals
- iii. Identify the particular ARVs that are being used to treat pigs and/or other livestock

2.0 LITERATURE REVIEW

2.1 Pig farming in Uganda

According to the Uganda Bureau of Statistics and the Ministry of Agriculture, animal industry and fisheries, Uganda has about 3.2 million pigs, a number believed to be the highest in East Africa¹. Piggery is one of the fastest growing livestock enterprises especially in the rural areas owing to the relatively little capital requirements and the quick returns. To a great extent this is a major source of livelihoods especially for people of Oyam.

2.2 HIV Infection rates in Uganda.

Uganda's HIV/AIDS prevalence rate is increasing i.e. 6.4% in 2005 to 7.3% in 2012. According to the 2011 Uganda AIDS Indicator Survey (UAIS) report the percentage increase is higher among women than men. The prevalence rate has increased from 7.5% to 8.3% among women compared to 5-6.1% among men. Over 130,000 new HIV infections are recorded in the country each year². This means that more and more people will need ARVs in the coming years and their availability for treatment of pigs presents a conflicting objective.

2.3 Mechanism of action of ARVs

Anti retroviral therapy regimens are typically constructed using three or four drug classes based on their mechanisms of action in suppressing HIV replication: (Elion and Witt, 2003)

- 1) Nucleoside reverse transcriptase inhibitors (NRTIs),
- 2) Non-nucleoside reverse transcriptase inhibitors (NNRTIs),
- 3) Protease inhibitors (PIs).
- 4) Fusion inhibitor

http://www.agriculture.go.ug/userfiles/National%20Livestock%20Census%20Report%202009.pdf

¹Uganda Beaural of Statistics/The Ministry Of Agriculture Animal Industry & Fisheries: The National Livestock Census Report 2008. Kampala, Uganda; 2009:1–273.

²http://www.newvision.co.ug/news/632452-hiv-prevalence-rate-increases.html

Apart from HIV, certain ARVs like Tenofovir, lamivudine, and emtricitabine exhibit action against the Hepatitis B virus and are used in HIV/HBV co infection (Benhamou, 2004).

2.4 Fat redistribution properties of ARVs

Anti-retroviral drugs (ARVs) especially protease inhibitors are known to cause lipodystrophy – a condition denoting abnormal distribution of fat in the body (Dinges, *et al.*, 2005). HIV-associated lipodystrophy commonly presents with fat loss (lipoatrophy) in the face, buttocks, arms and legs, with accumulation (lipohypertrophy) in various body parts e.g. dorsocervical fat pad (buffalo hump) with circumferential expansion of the neck, in the breast and the abdomen. In some cases only lipoatrophy or lipohypertrophy may present and may not be related with ART (Dinges *et al.*, 2005), but protease inhibitors (PIs) and nucleoside reverse transcriptase inhibitor (NRTI) analogues are associated with a higher risk of lipodystrophy. Much as this is the case, in some cases incidences of only lipoatrophy are more common (Kalyanasundaram, *et al.*, 2012). If the farmers' objective is to fatten the pigs, then the opposite outcome (lipoatrophy) or a less appealing cosmetic appearance may be very likely to their disappointment.

2.5 African Swine Fever

Some virological geoepidemiological aspects of African swine fever have been likened to those expressed by HIV among other unrelated viral diseases (Lu, *et al.*, 2013), although these mechanisms remain not fully understood.

African swine fever (ASF) is a highly contagious viral disease with up to 100% mortality among domestic pigs. In endemic areas it causes serious socio-economic impact on people's livelihoods. Though there is paucity of information on the epidemiology of the disease in Uganda, ASF is highly endemic in Uganda (Kalenzi, *et al.*, 2003) and there appears to be no cost effective remedy in sight – effective treatment or vaccine (Penrith 2009).

African Swine Fever Virus is a double-stranded DNA virus with an icosahedral symmetry that belongs to genus *Asfivirus* and family *Asfarviridae* (Dixon, *et al.*, 2000).

ASF virus replicates in reticulo-endothelial cells. The epidemiology of ASF is direct and vector-borne (ticks) through a sylvatic (wild) and domestic cycles. The virus is highly resistant in tissues and the environment, contributing to its transmission over long distances through swill feeding and fomites. It is highly contagious and is transmitted by direct contact between infected pigs and susceptible ones or by contact with infectious secretions/excretions (Wilkinson, 1969).

3.0 METHODS AND MATERIALS

The study employed qualitative techniques to approach the study targets. Veterinary service providers under the leadership of the district veterinary officer and the district health workers under the leadership of the District Health Officer were convened for focus group discussions using an interview guide. Some farmers were visited and Observations were made on selected farms and a separate meeting was organized for farmers in one of the sub counties to discuss the practice and obtain the farmers opinions. Samples of ARVs being used by farmers on pigs were taken and submitted to Anyeke health center IV and to NDA drug registration department for identification. The data obtained was mainly qualitative.

3.1 Study area – Oyam District of Northern Uganda

Oyam county became a District on July 1st 2006, having been curved out of its mother district of Apac. It is located in the Northern part of Uganda between longitudes 32° 2′E, 32° 10′E and latitudes 2° 0′N, 2°7′N. It has a total population of 366,200 people. It is bordered by the Districts of Gulu in the North, Kiryandongo in the South West, Nwoya in the West, Apac in the South and Kole in the East. The district comprises of 12 sub counties i.e. Loro, Minakulu, Aber, Acaba, Ngai, Iceme, Otwal, Abok, Myene, Aleka, Kamdini, and Oyam Town Council. It has 61 parishes and 910 Villages. Oyam Town Council is divided into 2 (Two Wards) i.e. East Ward and West Ward with 12 Cells.³

³http://www.oyam.go.ug/aboutus.html

4.0 RESULTS

The reports of this practice in the area prompted concern from different stakeholders. For example the district administration of Oyam instituted an investigation led by the District Health Department, the District Internal Security Office (DISO) and the Police. By the time of the study there were no significant findings from these investigations. The results obtained by this study indicate that the reports of use of ARVs in pigs are authentic. Apart from ARVs certain other human drugs are also abused in the same way and veterinary drugs are also used on humans. These practices are supported by widespread self medication.

4.1 Use of ARVs in animals

According to the District veterinary officer, the first reports of this were brought to light in September 2013, when the DVO of Gulu was conducting a radio program on veterinary issues. Certain farmers from Kamdini called in and reported the practice. Following this, the press picked interest in the issue and had the DVO of Gulu interviewed for technical opinion prior to the publication of the news article.

The veterinary service providers in the focus group discussion confirmed that the use of ARVs in pigs is a common practice in Oyam. Unlike the media reports that focused on fattening pigs, ARVs are mainly used to treat African Swine Fever (ASF) in pigs, also locally nicknamed "*Pig Ebola*", a disease that has no remedy at present in Uganda. Attempts have also been made to use ARVs against New Castle Disease (NCD) in chicken and fattening of cattle.

The dosage followed by farmers was not precisely established. For example, some farmers gave one tablet to each affected pig for three consecutive days while some gave one tablet once, and they claimed that the results were very promising. For example in Minakulo one veterinary service provider also a member of the research team physically witnessed a farmer administering ARVs to pigs. The farmer picked the ARVs crushed them in water and gave them to three pigs that had been clinically diagnosed with African Swine Fever. One of them died but the two recovered.

A follow up investigation in Kamdini was made to interact with the farmer who initiated this practice in the area. This farmer had an outbreak of African Swine Fever on his farm. He approached a widow whose husband had died of HIV/AIDS who gave him three different types of tins full of ARVs that belonged to her late husband. The farmer administered one tablet per pig daily for the first three days and all the pigs recovered. He went ahead and did the same for his friend whose pig was emaciated and was not eating well. The emaciated pig started eating well, became very active and started gaining weight. The farmer was motivated to experiment ARVs on pigs after knowing that HIV and ASF are both viral diseases, without a cure and if emaciated people are started on ARVs they gain weight very quickly.

During a focused group discussion held at Iceme sub-county head-quarter, farmers confessed having used ARVs to fatten their pigs while others had witnessed fellow farmers administer ARVs to pigs suffering from African swine fever.

One of the farmers also a civil servant admitted having used ARVs to treat her pigs which were suffering from African swine fever. These pigs were there at the time of the visit and are shown in the picture below.



Figure 1: Photo showing some of the pigs claimed to have cured of African Swine Fever after giving them ARVs

The discussion with farmers revealed that a good number of them know the basic clinical signs of ASF. Among the signs they enumerated were: loss of appetite, reddening of the skin, shivering and diarrhea especially in the piglets. Some of the cases were examined by Veterinarians who clinically diagnosed ASF. No laboratory confirmation had been done to confirm the disease.

4.2 Types of ARVs used for treatment of animals

Attempts were made to obtain samples of ARVs that the farmers used for treatment of animals. Most farmers did not live to their promise to provide us with the samples. However some tablets were recovered as shown in the photo below. Since the tablets were not in their packs, it was not easy to identify them precisely. At the ART clinic, these samples were compared with the available ARV packs and one of them was identified as Nevirapine 200mg (single ingredient), a white caplet with a line in the middle and embossed with C 35. The samples were not adequate for laboratory investigation to attain definite chemical identification.





The farmers preferred the white tablets and they claimed that they were very effective (*strong*) as compared with the blue ones. They said that the blue tablets were weaker. The tablets shown above are white, but the blue ones found at the ART clinic also

contained Nevirapine 200mg among other ingredients – Zidovudine and Lamivudine 150mg. Therefore the logic behind this preference was not established.

There had been attempts by some farmers to befriend some health workers in order to access ARVs for treatment of livestock. One official in the District Health Office had a personal experience of the vice. During the outbreak of New Castle Disease (NCD), all his chicken were attacked by the disease. One of his friends - a farmer advised him to use ARVs to treat the chicken since by virtue of his job he had access to ARVs, to which he objected. This farmer kept begging him to get for him some ARVs to treat his chicken too but he refused. The farmer even specified the type of ARVs he wanted—a brand with a fixed dose combination (FDC) of Zidovudine, Lamivudine and Nevirapine, for adults.



Fig. 3: One of the blue tablets the farmers claimed are not as effective in treatment of ASF

4.2 Source of ARVs used to treat animals

4.2.1 ART programs in Oyam district:

Enrollment of patients on ART in Oyam follows the policy guidelines as established by Ministry of Health. There are 5 centers in the district, namely: Aber hospital, Anyeke Helath Center IV, Agururude Health center III, Otwal Health center III, and Ngai Health

Center III. Some Private-Not-For-Profit health centers have also been added. These include: Iceme Health Center III (Catholic), and Minakulo Health Center III.

Farmers indicated that they obtain the drugs from those who collect them from the health centers- the patients or their caretakers. During a focused group discussion with the farmers it was found out that the main way to access these ARVs was through people on ART from whom they are bought. Some farmers on ART also shared their dose with their pigs for fattening and treatment of ASF.

According to the District health office, some patients on ARVs have officially known caretakers who among others duties may assist in collecting the ARVs from the health centers and delivering them to the patients and encouraging them to take the drugs in order to improve adherence which is reportedly low. Apart from the caretakers, the district has village health teams which were trained by Northern Uganda Health Integration to Enhance Services (NU-HITES) to support ART clinics. They make follow-up on ART patients for adherence and sometimes deliver the drugs to the patients up to their homes.

Caretakers of People Living With HIV AIDS were a main focus as a possible avenue through which ARVs are channeled to other uses. When the patient relocates to another place, or in the unfortunate case of death, some caretakers continue to collect ARVs for the patient, which are then diverted to treatment of animals. One veterinary service provider in whose presence the ARVs were administered to the pigs said that the farmer involved had a brother who was on ARVs, of whom she was the caretaker. The brother had since relocated to South Sudan. The farmer continued to collect the patient packs from the health center for her brother and diverted them to treatment of pigs.

There is a mechanism to handle transfer of patients from one center to another using transfer forms. This is however not always followed as the process is not always quick let alone being efficient and some patients end up being frustrated. Some patients are not aware of the process and end up facing a lot of inconvenience. To come around this inconvenience, some patients enroll anew as they relocate and deny ever having been

on any ART. Such cases are common and are suspected when the patient posts a rather high CD4 count indicating that they have been on ART.

On the other hand, patients have a tendency of registering in more than one center. They continue picking drugs from all the centers and pile stock. This ensures that they never ran out of drugs since their life depends on the drugs. It is this excess that could be used on pigs and other livestock. At the time, there was no system in place to prevent double or triple enrollment of patients on ART and besides this, ARV stock outs are common in the area.

In some instances patients prefer enrolling in centers far away from their villages where no one knows them for fear of stigma. This is common for men. Some of them send their wives instead of attending the clinics personally. During the time of insurgency, some people were lured to some centers in Gulu because of the relief aid that accompanied the ART program in these centers. Since such patients come from far, their follow up becomes rather difficult.

4.2.2 Adherence to treatment.

Adherence in Oyam is estimated at about 85%, much lower than the optimal 95%. The low adherence was blamed on the adverse drug reactions following commencement of ART. To some patients, even counseling could not ensure improved adherence. Some patients had given up with life and had resorted to drinking to forget their predicament. Due to low adherence, excess packs of ARVs are left and diverted to treatment of pigs.

4.2.3 Storage facilities for drugs:

Improper storage systems and facilities for ARVs within the district were identified as a possible factor. It was common for ARVs to expire in storage because most of them were received as donations with short expiry. There was no system in place for periodic collection and destruction of such drugs, mainly due to erratic transport and other logistical challenges at the district. It is possible that some of these expired drugs may find their way into the hands of the farmers for treatment of pigs and other livestock.

4.3 Community perception of the problem and local factors leading to the practice

Oyam is one of the districts of Lango sub region of Northern Uganda. It is one of the areas greatly affected by the long insurgency of Joseph Kony which destroyed much of their livelihood. Livestock especially cattle were part of the livelihood here. These were decimated during the war. People are now concentrating on the smaller livestock which offer quicker returns.

Most people in the area are into pig farming. There are no definite statistics on pig population in the district, but they are mainly reared using the free range system. In areas near towns, farmers could buy piglets, identify them by notches on the ears and release them into the towns to scavenge, only to be captured when they are ready for slaughter. Capturing these free ranged pigs was not an easy exercise as it involved running all over, with the help of neighbors. Pigs roam the villages and towns alike which was believed to be a factor in the prevalence of African Swine Fever, for which ARVs are used.

Through a visit made to one of the local markets in Amwa which operates every Monday, and interaction with the local people in small towns along the Kamdini Lira road, it was found out that the local people were not bothered about the dangers of the practice of using ARVs in pigs or other livestock. In the local periodic markets, pigs and pork are sold as any other livestock or meat. Indeed pork was being sold by the road side on highways and passersby could stop and buy sticks of pork roast as they go on their journeys. It is one of the main meats consumed and constitutes a major livestock sold in livestock markets. This was a contrasting finding compared with the other towns in Uganda where pork is not sold in open places in towns.



Figure 4: Locals enjoying pork roast at the road side in **Iceme Trading** center, Oyam District. In many cases adequate cooking is not achieved before the meat is consumed, raising more safety issues.

The Kamdini-Lira-Gulu- Oyam area is particularly known for pig rearing. This and many other areas of Northern Uganda have taken on piggery as a quick money generating livestock enterprise, also strongly supported by several post-insurgency reconstruction programs.

There is high market for pigs in this area. Pigs cost dearly and each piglet goes for a total of UGx 50,000/= (USD 20) on average. This demand is sustained by the lucrative market in South Sudan. This has led many households to rear pigs which they can't afford to lose to African Swine Fever, hence the practice of administering ARVs to them.

There is a belief in the community that pigs have an element that reduces the effect of HIV in people. So some people eat pork for this purpose regardless of their religious inclination. This view is held by people in several other places apart from Oyam.

4.4 Other human drugs used in livestock for different purposes

The participants of the Focus Group Discussions revealed the extent of the problem of use of human drugs for treating animals. The table below shows some of the other human drugs used on animals in Oyam and their "indications".

Table 1: Common human drugs that have been used in livestock in Oyam

Drug	Species	Use/indication
Expired Procaine	Cattle	For topical application on wounds inflicted
Penicilin forte (PPF)		commonly during training for ploughing
Cotrimoxazole (Septrin)	Pigs	African Swine Fever
Metronidazole (flagyl)	Chicken	Diarrhea and respiratory infections, New Castle
		Disease
Chloroquine	Chicken	Diarrhea and respiratory infections, coccidiosis
Rifampicin	Various	Diarrhea
Amodium	Goats	Diarrhea
Indocid (indomethacine)	Rats	Kill rats
Water guard	Chicken	Newcastle disease

There is also a practice of using Paracetamol to cook the feet of cattle popularly known as "*Mulokoni*". It was also reported as a common practice in schools for cooking beans. Paracetamol is reported to be used as a tenderizer for hard foods to cook quickly.

Apart from conventional drugs, farmers use marijuana to increase the appetite of the animals so that they can gain weight very quickly. It has been observed that animals given a dose of marijuana eat compulsively and gain weight in a very short time.

5.0 DISCUSSION

The use of drugs that have been hitherto preserved for the specific treatment of HIV/AIDS in humans for food producing animals is per se a weird experimentation. The practice represents an unnecessary exposure of the public to ARVs through the food chain as residues. This is a high level of irrational drug use which may have different risks for different sections of the population. The concern here is the likely effect of the exposures to HIV positive individuals who are not yet on ART, which may accelerate drug resistance, rendering the ARVs less effective.

For the rest of the consumers, there is a concern of toxicities or side effects as maximum residue limits are not established for this particular group of drugs in the animal foods of concern, and there is likely to be no regard to withdrawal periods. The incidence further reinforces the need for better organization and control in the animal food value chain and in particular food safety controls. Much as this may be known there is no organized food control system that can stop such practices.

On the other hand the safety of the ARVs on the health of the animals is not assured since their use in animals has not been clinically tested or approved.

There are many stakeholders in the national and international HIV/AIDS programs. Much of the support comes from donors, since anti retroviral therapy is too expensive for Governments in the developing world to shoulder. Such reports may affect the attitude of donors towards supporting the programs which may be detrimental for the sustainability of the programs.

At a local level, systems through which the farmers obtain these drugs for use in pigs represent loopholes which ought to be worked on. The possibility of registering one patient in more than one ART centers indicates that the system in place cannot detect duplication and abuse. The excess drugs so obtained may not only be used for treating animals but may also be put to other uses detrimental to public health.

This study confirmed that some farmers actually share their medicines with their livestock. This makes the adherence suboptimal, making ART ineffective. This practice in essence denies a section of the public an opportunity to access drugs. Although this may not be felt at present, there is a fear that it may affect policy decisions by the supporters of the programs thereby condemning more lives. The willingness to sell off own drugs for short term gain means that the economic dimension of people on ART should be considered seriously during the design of the programs- the people may be considering poverty as a bigger problem than HIV and this affects adherence to treatment.

Poverty levels in this part of the country are very high, with the estimated annual household income of about \$100 (UBOS, 2010). This is partly due to the long

insurgence that ravaged this area, forcing people into Internally Displaced Peoples (IDP) camps. For effective ART, an adherence of more than 95% should be attained, to prevent resistance (Paterson, *et al.*, 2000). Unfortunately studies have shown that 95% of patients achieve suboptimal (<95%) adherence (Golin, *et al.*, 2002; Mannheimer, *et al.*, 2002; Howard, *et al.*, 2002; Ickovics, *et al.*, 2002; Walsh and Sherr, 2002).

Although the impact of HIV/AIDS on agriculture and livestock production in particular has been studied (Lagu, *et al.*, 2011; Engh, *et al.*, 2000) the health service programs have not been considering livestock health as a factor in the success of public health objectives. This is a classical example where animal diseases are likely to directly affect HIV/AIDS programs in a very drastic way. A broader analysis of this is needed.

Nevirapine and the fixed dose combination Zidovudine +Lamivudine + Nevirapine one of those identified being used in the area, is a Reverse Transcriptase Inhibitor combination. The action of these three members of this combination should be analyzed in relation to the virology of African Swine Fever and New Castle Disease on which this combination was claimed to be have effect.

6.0 CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1. Conclusions

- i. The reports of use of ARVs in fattening of pigs were found to be authentic. The practice is widespread in Oyam and perhaps other neighboring districts. Although the reports focused on fattening of pigs, ARVs are used more for treatment of African Swine Fever. Other dangerous malpractices e.g. use of paracetamol to cook for the public and in schools is another danger which may have serious public health effects.
- ii. Absence of a conventional remedy for ASF, the free range production and poor marketing systems of pigs coupled with lack of plausible controls in the ART programs are key factors that have led to the practice of use of ARVs in treatment of pigs.

iii. No much conclusion can be made on the particular ARVs used. May be the farmers have not yet reached this level of precision and the dosages are not definitely established.

6.2. Recommendations

Farmers are always experimenting on many things. As far as drugs are concerned, veterinary pharmacovigilance is vital to bring such practices to the attention of various stakeholders. Such experimentations may also serve as an eye opener on which scientific breakthrough can be built to solve some problems. Although this practice is highly discouraged, this particular experience should incite scientists to study the claims of efficacy of ARVs on African Swine Fever and other viral diseases of livestock. A detailed and highly controlled study should be conducted to ascertain the claims of the farmers regarding the efficacy of ARVs in treatment of African Swine Fever.

Direct and indirect socioeconomic and public health dimensions of livestock diseases should not be overlooked in the design of programmes. Thorough risk analyses are a pre-requisite.

The widespread and growing malpractice of irrational use of medicines should be investigated further. In particular, use of Paracetamol in cooking should be investigated.

6.3 Limitations

These findings were not based on confirmatory diagnosis of the diseases of livestock the farmers claim the ARVs cure. It was also not possible to pinpoint with precision the particular ARVs that are effective against the identified diseases. Although much effort and tact was employed to be able to win the farmers' confidence and cooperation, the research team was not able to obtain adequate samples, as the people involved were a bit secretive. As a result, no tins or packs were obtained and thus laboratory analysis could not be carried out.

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