Safe Drugs Save Lives

GUIDELINES ON VETERINARY PHARMACOVIGILANCE IN UGANDA

(Detecting and Reporting Veterinary Adverse Drug Events)

National Drug Authority
Head Office
Rumee Towers
Plot 19, Lumumba Avenue
P. O. Box 23096
Kampala, Uganda.
Tel: +256-417788100
E-mail: vet@nda.or.ug, ndaug@nda.or.ug
Website: http://www.nda.or.ug

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These guidelines shall be cited as the *"Professional Guidelines on Veterinary Pharmacovigilance in Uganda (Detecting and Reporting Veterinary Adverse Drug Events), Doc. No. DPS/GDL/031, Revision No. 0."*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these Professional **"Guidelines on Veterinary Pharmacovigilance in Uganda (Detecting and Reporting Veterinary Adverse Drug Events),** Doc. No. DPS/GDL/031 Revision No.: 0", made this 9th day of December 2020, that take effect on 21st December 2020

Signature

Dr. Medard Bitekyerezo

CHAIRPERSON

National Drug Authority

Kampala, Uganda

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1.0 INTRODUCTION

1.1 Background

Veterinary pharmacovigilance concerns monitoring, evaluating and improving the safety of veterinary drugs, with particular reference to adverse events in animals and human beings related to the use of these drugs. It also involves collection of information on adverse events due to off-label use and investigations of the validity of the withdrawal period and of potential environmental problems.

Approval of drugs for market authorization depends on the decision that the benefit of the drug out weights its risks, based on information that accrues from pre-approval studies. These studies are incapable of detecting all of the negative effects of the drug.

As such, veterinary drugs will have the propensity to cause several previously unknown adverse reactions. It's therefore imperative that these drugs are vigilantly monitored post market approval to identify, remediate and communicate such negative effects as a means of enhancing patient safety and improving treatment outcomes.

This guideline highlights the processes and roles of each player in the veterinary pharmacovigilance system in Uganda, and focuses on the spontaneous methods of drug safety monitoring.

1.2 Mandate

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs. The National drug Policy and Authority (pharmacovigilance) regulations 2014, provide for routine monitoring of the safety of drugs.

These guidelines describe the requirements set by NDA, for animal health care professionals, animal owners, caretakers and holders of the certificates of registration to report to NDA adverse drug events and any drug related problems.

1.3 Rationale

It is important to continually monitor the safety and efficacy of a drug after registration. The information collected allows the on-going assessment of the benefit-risk of the drug in relation to its target population and throughout its life-cycle. The existence of a reliable pharmacovigilance system supports the benefit-risk assessment approach to licensing, and avoids the drawbacks of a zero risk approach.

Information on safety and efficacy of a veterinary drug at market authorization is limited to pre-marketing evaluation and clinical trials, which have the following limitations:

i) The animal population in clinical trials is very selective and limited.

ii) The duration of clinical trial is too short.

iii) Differences between countries, which leads to variation in patient factors, variation in drug utilization and drug manufacturing processes.

It is therefore possible that pre-market studies are unlikely to capture rare but serious adverse events, toxicity and adverse experiences during use in different age groups, species, breeds production systems and physiological statuses, hence the need for pharmacovigilance.

1.4 Purpose of the guidelines

To further guide the process of identification, investigation and diagnosis of Adverse Drug Events in animals, human handlers and possible environmental effects

1.5 Objectives of the guidelines

i) To detect early unknown safety problems related to use of veterinary drugs
ii) To prevent patients or handlers from being affected unnecessarily
iii) To detect unexpected therapeutic benefits
iv) To detect increases in frequency of known adverse effects to veterinary drugs
v) To identify risk factors associated with use of veterinary drugs
vi) To Quantify risks related to use of veterinary drugs

1.6 Scope

These guidelines apply to all veterinary drugs used in Uganda. This also includes traditional and complementary drugs for which marketing authorisation has been duly granted for veterinary use. It includes counterfeits, and other drugs not authorised by NDA but that may illegally find their way to the market and may cause a reaction.

1.7 Policy

Statutory Instrument 37: National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014 provide that health care professionals (human and animal) shall report any serious adverse drug event that arises during the process of providing health care.

These guidelines are drawn under section 6 and 7 of the National Drug Policy and Authority (Pharmacovigilance) Regulations, SI No. 37, of 2014 and incorporating recommendations of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

2.0 TERMS AND DEFINITIONS

The definitions provided below apply to the words and phrases used in these guidelines.

*"**Act**"* means the National Drug Policy and Authority Act, Cap. 206

*"**Adverse Drug Event (ADE)**"* means any unwanted medical occurrence in a subject to whom (which) a drug is administered and includes an occurrence which is not caused by or relates to the drug. Included are events related to suspect lack of expected efficacy according to approved labelling or noxious reactions in humans after being exposed to the drug.

"Adverse drug reaction (ADR)" means a response to a drug which is noxious and unintended and which occurs at doses normally used in animals for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.

"Adverse Drug Event Report (ADER)" means a direct communication from a reporter that includes at least an identifiable reporter, animal(s) or human(s), drug and one or more adverse events.

*"**Counterfeit drug**"* means a drug that is deliberately or fraudulently mislabelled with respect to its identity, content or source.

*"**Drug**" any substance or preparation used or intended to be used for internal or external application to the animal body either in the treatment or prevention of disease or for improving physiological functions.*

*"**Licensed person**"* means a person licensed under section 14 of the Act.

*"**Pharmacovigilance**"* means the science and activities related to the detection, investigation, assessment, understanding and prevention of adverse effects or any other possible drug–related problems.

*"**Serious Adverse Drug Event**"* means any drug related event which results in death, is life-threatening, and results in persistent or significant disability / incapacity, or a congenital anomaly or birth defect. For animals managed and treated as a group, only an increased incidence of serious adverse events as defined above exceeding the rates normally expected in that particular group is considered a serious adverse event.

*"**Signal**"* means reported information on a possible causal relationship between an adverse drug event and a drug, the relationship being unknown or incompletely documented previously. Usually, more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

*"**Unexpected Adverse Drug Event**"* means an adverse event of which the nature, severity or outcome is not consistent with approved labelling or approved documents describing expected adverse events for a drug.

3.0 ABBREVIATIONS AND ACRONYMS

ADE	Adverse Drug Event
ADER	Adverse Drug Event Report
ADR	Adverse Drug Reaction
HCR	Holder of the Certificate of Registration
NDA	National Drug Authority
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products

4.0 THE VETERINARY PHARMACOVIGILANCE SYSTEM

4.1 Methods of veterinary pharmacovigilance

The main methods of pharmacovigilance include:

i) Passive surveillance: this entails spontaneous / voluntary reporting system where no active effort is employed to look out for ADEs.

ii) Active surveillance: this is where active effort is employed to collect and analyse adverse drug events. It can take the forms of Post-Marketing Surveillance (PMS), prescription event monitoring, cohort studies, intensive / targeted hospital monitoring, case -control studies, record–linkage etc.

4.2 Who should report Adverse Drug Events

All animal health care professionals and any other users of veterinary medicines or stock remedies can report adverse drug events or problems related to use of drugs in animals. Although reporting via the attending veterinarian is encouraged, an Adverse Drug Event Report or drug related problem may be initiated by anyone directly involved with the purported adverse drug event or drug problem including the farmer or animal owner.

Reporters therefore include the following:

a) All animal health care professionals

b) Animal health institutions using veterinary drugs (government and private veterinary clinics, veterinary pharmacies, and research and education institutions)

c) Holders of the certificate of registration (manufacturers and / or their local agents)

d) Animal owners and care takers

4.3 What to report

4.3.1 Adverse drug Events and reactions in animals, human handlers and the environment

Report all suspected adverse drug events on all drugs including vaccines known or unknown, serious or minor, that are noxious (harmful) and unintended, including lack of efficacy, which occur at any dose including the normal, overdose, misuse or malice / accidental poisoning and suspected substandard drugs. Any ADE recognised in the animal or human handler should be reported even if you are not certain that the drug caused the ADE or even if you do not have all the details.

4.3.2 Therapeutic failure

For all drugs (new or old) with suspected unexpected lack of efficacy should be reported. The sample (if available) should be attached to the report. Lack of efficacy may imply that either; the medicine is of poor quality, there is an interaction, there is resistance or the drug is a counterfeit.

4.3.3 Unexpected therapeutic benefit

Some side effects of certain drugs or other technologies may work to the advantage of patients, clinicians and farmers in unanticipated ways. These bonus effects may be overlooked or only brought to light after a long delay. Such benefits may actually lead to drug abuse with a risk of further ADEs if not scientifically evaluated.

Although criteria for accepting new developments into animal health services may eliminate or discourage treatments that could in the longer term prove to be highly beneficial, capturing these observations through the pharmacovigilance system is the beginning point. Examples of these may be hyperphagia/polyphagia, relief of symptoms of untargeted diseases and conditions, higher activity, etc.

4.3.4 Drugs of questionable quality

Report drug quality concerns such as:

i) Suspected contamination
ii) Questionable stability
iii) Defective components
iv) Poor packaging or labelling
v) Expired drugs

Whenever you suspect that a drug is of poor quality, report as soon as possible to the regional inspector of drugs, or NDA head office through the contacts herein or to any NDA regional offices, where the complaint can be handled using the Market Complaint Form (Appendix II Form Number QMS/FOM/013).

4.4 Efficient ADE reporting and reporting timelines

An adverse drug event should be reported soon after it occurs. A recent event is easier to report and the report is more likely to be accurate. A decision to report should be done as soon as the ADE is noticed or notified in an animal or human (handler or consumer of animal product), so that adequate observations and information can be freshly obtained from the affected animal patient and/or handler, and the reporting form filled. The following are the basic principles of efficient reporting:

i) Report the adverse event immediately after it occurs. For reports on serious adverse events, within 24 to 48 hours of notification.

ii) If possible, take the decision to report while the patient animal is still with you, which gives a chance to the reporter to clear any ambiguity by re-questioning the owner or examining the patient animal

iii) Think about any other factors which may contribute in causing the event such as: other prescribed drugs, self-medication, herbal drugs, feed, chemicals

iv) For non-serious adverse events report as soon as possible but in any case not later than 15 days

4.5 How to recognise Adverse Drug Events / Drug related problems in animals

Adverse Drug Events are difficult and sometimes impossible to distinguish from the disease being treated since they may act through the same physiological and pathological pathways.

The following stepwise approach may be helpful in assessing possible ADEs:

i) Take proper history and conduct proper examination of the animal.

ii) Ensure that the drug ordered is the drug that was received and actually given to the animal at the dose advised.

iii) Verify that the onset of the suspected ADE was after the drug was taken, not before and discuss carefully the observation made by the animal owner.

iv) Evaluate the suspected ADE after discontinuing the drugs or reducing the dose and monitor the animal's status (De-challenge). If appropriate, restart the drug treatment and monitor recurrence of any adverse events (Re-challenge).

v) Analyze the other alternative/possible causes (other than the drug) that could on their own have caused the reaction or problem.

vi) Use relevant up-to date literature and personal experience as a veterinary professional on drugs and their ADEs and verify if there are previous conclusive reports on this event.

4.6 Reporting by farmers, animal owners and caretakers

Farmers, animal owners and caretakers may report to National Drug Authority any ADEs attributable to use of particular veterinary drugs via the following channels.

i) Telephone call – toll free line 0800101999

ii) Whatsapp message on: 0791 415555

iii) Any Written form of document

iv) E mail: vet@nda.or.ug or druginfo@nda.or.ug

v) The event may also be captured through other forms of media.

As much as possible reporters in this category must provide active contacts (telephone or otherwise) through which they can be reached for further management of the reports.

National Drug Authority on receiving such reports may contact the area veterinary office or the attending health care professional who then generates an ADER using the official ADE form (Appendix I) and transmits it to NDA.

4.7 Reporting by animal health care professional

Animal health care professionals or licensed persons are obliged by the National Drug Policy and Authority (Pharmacovigilance) Regulations to directly and immediately submit ADERs to NDA using the official form, on recognition of any suspected serious ADE. Additionally, they should notify the Holder of the Certificate of Registration (HCR) who is also obliged to report to NDA on receipt of such report. The Holder of the Certificate of Registration also compiles the safety reports in order to meet their obligation as per DPS/GDL/034

Clear contacts of the reporter and the animal owner or handler are important for feedback and clarification during causality assessment.

Acknowledgement of receipt and feedback to the reporters shall be given by NDA through the appropriate channels within 5 days of receipt of the report or as the occasion may demand.

4.8 Format of the ADE report

The ADE reporting form is designed to capture the basic information about the person submitting the report, the animal owner, the animal patient, description of the suspected veterinary drug, the description of adverse drug event and the actions so far taken.

The information to be included in the form is considered essential and should as much as possible be complete. Incomplete information however should not prevent the reporter from submitting the report with the information obtainable so far. Minimum information should entail identifiable animal, herd or flock, identifiable drug product, the reaction /adverse effect observed as well as the contact of the reporter.

While completing the form, avoid non-standard abbreviations and write clearly. Alternatively, a soft copy of the form can be used by filling in the text-active fields/dialogue boxes.

Use a separate form for each defined case (affected individual, herd or flock). A follow-up case for previously reported case should be indicated.

4.9 The safety issue being reported

The safety issue being reported may be in animal patient, human patient, or an environmental problem. It may be lack of expected efficacy or arising from defaulting the recommended withdrawal period, which is a food safety issue.

4.10 Particulars of the reporter

These are indicated for follow up and additional information during causality assessment and feedback. Entries in this section are also useful for mapping out ADEs and compare possible geographical factors during causality assessment. The following should be clearly indicated:

a) The name of the reporter

b) Whether the reporter is a veterinarian, pharmacist or other professional.

c) The district and telephone number of the reporter are crucial details that should be included.

4.11 Details of owner or caretaker of or the patient(s)

For purposes of proper documentation of the ADE, the details of the owner or caretaker of the animal should be properly captured. This is because s(he) is the person in closest contact with the case who could observe the progress of the ADE under the guidance of the attending animal health care professional. The following information should be captured:

a) Names of the owner,

b) Physical Location; village, Parish, sub – county, District,

c) Telephone number and email.

4.12 Details of patient

The details of the patient (animal(s) or human(s), suffering from the ADE should be given. Proper identification of the animal(s) involved is crucial indicating the species, breed, sex, (pregnant, neutered), age and weight (for human patient, only age and sex are required). In cases where the animal has names or identification tag and colour, these should be indicated on the reporting form or on additional sheets. The reason or the purpose for treatment is stated as the condition being treated. Other reasons may be for improvement of production, prophylaxis, etc.

4.13 Details of suspected drug

The veterinary drug administered before the suspected adverse drug event should be fully described and identified. Here, the following should be indicated:

a) Name of the drug administered

b) Pharmaceutical form & strength (ex: 100 mg tablets). Pharmaceutical forms include tablet/bolus, drench, injectable, spray, dip, ointment etc.

c) The Manufacturer as indicated on the drug pack should be given; Batch number, expiry date, route/site of administration, dose given so far and frequency, duration of treatment / exposure denoting the start date and end date.

d) The person who administered the drug(s)- veterinarian, owner, etc should also be indicated.

It is important that the holder of the certificate of registration should be informed through their local agent of the adverse drug event and this should be indicated on the report form.

4.14 Description of the suspected Adverse Drug Event(s)

The suspected ADE should be described concisely. The description should include the number of animal (or humans) exposed, the number reacting (where reacting also includes not responding in case of animal cases), the number that died and the number that recovered. This gives an indication of the seriousness of the ADE.

Indication of the date the ADE was recognized is crucial. This date is compared with the date the treatment was started, information that is very useful during causality assessment.

The medical condition prior to administration of the suspected drug is also indicated, basing on the clinical diagnosis or otherwise by the attending veterinarian.

The reporter should describe the clinical manifestation of ADE. This includes description of the event or problem in terms of nature of reaction / lack of efficacy. Here as much information should be given in this field - immediate or delayed reactions, the nature, localization or generalization, severity and characterization. Other reaction details that are delayed reactions should also be noted. In case of an immunological product, the previous vaccination history should be given.

The treatments given to remediate the ADE should be indicated in the space for "action taken". The effect observed on discontinuation (de-challenge) and re-introduction (re-challenge) of the suspected drug where applicable should be given. Any post mortem and laboratory findings should be indicated and relevant documents attached.

In case of human cases, the mode of exposure should be given. This may take the form of contact with treated animal, oral ingestion, topical exposure, ocular, inhalation or injection. In cases where such incidents are deliberate, this should be indicated. The attachments here should include the medical examination forms and diagnostic tests results carried out if accessible.

4.15 Where to obtain and submit reporting forms

Reporting forms (Appendix I and II) can be obtained from the centres listed below or downloaded from the NDA website www.nda.or.ug

i) Registered and licensed veterinary drug outlets, clinics and hospitals
ii) Commissioner Animal Health
iii) Uganda Veterinary Board
iv) Veterinary training Institutions
v) Districts Veterinary Offices

4.16 Delivery of completed ADER forms

Filled ADERs may be scanned and transmitted to NDA by the following means;

i) E mail: vet@nda.or.ug; or druginfo@nda.or.ug
ii) Whatsapp number 0791 415555 or any other given from time to time;
iii) National Drug Authority Head Office, Rumee towers, Plot 19 Lumumba Avenue P.O. Box 23096, Kampala;
iv) Tel: +256-417788100; or
v) delivered physically or by post to the NDA regional offices indicated hereunder:

Central Region Office - Kampala
Plot 1-2 Jinja road
Premier Complex Building, Nakawa
P.O. Box 40082, Kampala
Tel: +256 312 261 584

Northern Region Office - Lira
Plot 48 Ogwal, Ajungu road
P.O. Box 235, Lira
Tel/Fax: +256 473 420 652

West Nile Region Office - Arua
P.O.Box 1034, Arua Plot 1
Mt Wati Road at Anyafio
Tel: +256 372 260 087

Western Region Office – Hoima
Muganwa Center
Plot 30 Old Tooro road
P.O. Box 192, Hoima
Tel/Fax: +256 465 440 688

Eastern Region Office - Tororo
Plot No. 26 Kwapa road
P.O. Box 453, Tororo
Tel/Fax: +256 454 445 195

South Eastern Region Office - Jinja
Plot 64 Gokhale Road
P.O. box 1710, Jinja Municipality
Tel/Fax: +256 434 122 176

South Western Region Office - Mbarara
Plot 26 Johnstone Road
Boma (After Boma Primary School)
P.O.Box 1886 Mbarara Municipality
Tel: 0485 421 088
Fax: 0485 421 220

5.0 REFERENCES

1) National Drug Authority Professional Guidelines on submitting periodic safety update reports and any other reports that may be relevant to determine the safety, efficacy and quality of a drug, Doc. No. DPS/GDL/034
2) The National Drug Policy and Authority (Pharmacovigilance) Regulations 2014
3) The National Drug Policy and Authority (registration) Regulations 2014
4) National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition)
5) Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERS) 2015 VICH GL24 (PHARMACOVIGILANCE: AERS)

APPENDIX I: VETERINARY ADVERSE DRUG EVENT REPORTING FORM

National Drug Authority
Plot No. 19 Rumee Towers, Lumumba Avenue
P.O. Box 23096, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
Tel: +256-417788100

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VETERINARY ADVERSE DRUG EVENT REPORTING FORM

SAFETY ISSUE	**NAME AND ADDRESS OF REPORTER**	**DETAILS OF OWNER (/affected)**
In animals ☐ **In humans** ☐ **Environmental problems** ☐	Veterinarian ☐ Pharmacist ☐ AHO ☐ Other ..... Name: District: Telephone : Email:	Name: Village: Parish: Sub county: District: Telephone

PATIENT(S) Animal(s) ☐ Humans ☐ (for humans fill only age and sex below) **New case** ☐ **Follow up case** ☐

Species	**ID (tag)**	**Breed**	**Sex**	**Status**	**Age**	**Weight**	**Reason for treatment**
			Female ☐ Male ☐	Neutered .Yes ☐ No ☐ Pregnant Yes ☐ No ☐			

SUSPECTED DRUG ADMINISTERED BEFORE THE ADVERSE DRUG EVENT
(if more products are administered concurrently than the number of boxes available, please duplicate this form)

Name of the drug administered			
Pharmaceutical form & strength (ex: 100 mg tablets)			
Manufacturer			
Batch number		Expiry date	
Route/site of administration		Dose / Frequency	
Duration of treatment / Exposure:	Start Date	End Date	Duration:
Who administered the drug? (veterinarian, owner, other)			
Has the holder of the certificate of registration been informed?	Yes ☐	No ☐	
Concomitant products administered (include dosage)	1.	2.	

DESCRIPTION OF THE SUSPECTED ADVERSE DRUG EVENT *(see notes overleaf)*

No. exposed	No. reacting	No. died	No. recovered	Date ADE recognised

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Medical condition prior to administration **Clinical manifestation of ADE**	
Action taken	

HUMAN CASE (*If the reported case refers to a human being, please also complete the details of exposure below)*

Contact with treated animal ☐	Oral ingestion ☐	Topical ☐	Ocular ☐	Inhalation ☐
Injection exposure: Finger ☐	Hand ☐	Joint ☐	Other ☐	

Exposure dose of suspected drug:

Name ..... Signature ..... Date .....

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APPENDIX II: MARKET COMPLAINT FORM

National Drug Authority
Plot No. 19 Rumee Towers
Lumumba Avenue, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
+256-791415555; Uganda National Drug Authority

The Republic of Uganda
Ministry of Health

Safe Drugs Save Lives

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Market Complaint Report Form – Part 1

Complaint Number *(To be inserted by NDA)*	**Date complaint received at NDA** *(To be inserted by NDA)*

1.0	**LOGGING IN OF THE COMPLAINT** *(To be completed by client/customer/stakeholder/interested party/anybody)*	
1.1	**Name of complainant**	1.2 **Designation / Occupation**
1.3	**Name of institution:**	
1.4	**Location address:**	
1.5	**Tel. No.:**	**Email address:**
1.6	**Type of Complaint:** *(Check whichever is applicable by double clicking on the box)* **Drug Product Complaint** ☐ **Complaint about NDA** ☐ **Other** ☐ *(Please Specify)*	
1.7	**Nature of product complaint** *(Check whichever is applicable)* Quality ☐ Suspected Counterfeit ☐ Efficacy ☐ Expired ☐ Labeling ☐ Packaging ☐ Other ☐ *(Please Specify)*:_____	
1.8	**Product Category** (Check whichever is applicable) Drug ☐ Herbal Medicine ☐ Sundries ☐ Medical Device ☐ Other ☐ *(Please Specify)*	
1.9	**Product Details** *(Please fill whichever applies)*	

Name of Product:		Batch/Lot No:
Manufacturing Date:	Expiry date:	Dosage Form:
Name of manufacturer:		
Address:		

1.10	**Name & Address where product was obtained or bought**
1.11	**Description of the complaint** a) *Provide as much information as possible about the complaint and attach any available relevant information.* b) *Continue to the back of this page if you need more space.* c) *If complaint is about a product, provide a* ***sample*** *of the product or send a* ***photograph*** *on the WhatsApp number shown above.*

1.12	**Complaint Delivered to NDA Offices via** *(Check whichever is applicable)* Hand ☐ Email ☐ Telephone ☐ WhatsApp ☐ NDA Staff ☐ Feedback box ☐
1.13	**Have you logged a complaint about this issue before**: YES ☐ NO ☐
1.14	**If YES, when**?

6.0 DOCUMENT REVISION HISTORY

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9 Dec 2020	0	DPS/GDL/031	*Authors* Kayizzi Magembe Vincent Jeanne Muhindo Bukeka *Reviewers* Opira Wilfred Pamela Abwoyo Eseet Robert Musoke	First Issue of document

End of Document