Electronic Supplementary Material No.2

DRUG SAFETY JOURNAL

Targeted Spontaneous Reporting of suspected renal toxicity in patients undergoing Highly Active Anti-Retroviral Therapy in two public health facilities in Uganda.

Helen Ndagije[1], Victoria Nambasa[1], Elizabeth Namagala[2], Huldah Nassali[1], Dan Kajungu[3], Gordon Sematiko[1], Sten Olsson[4], Shanthi Pal[5]

[1]National Pharmacovigilance Centre, National Drug Authority, Kampala Uganda

[2]STD/AIDS Control Program, Ministry of Health, Kampala Uganda

[3]Institute of Health and Society (IRSS), Universite Catholique de Louvain, Brussels, Belgium

[4]World Health Organisation Collaborating Centre for International Drug Monitoring, Uppsala, Sweden

[5]World Health Organisation

Corresponding Author: Helen Byomire Ndagije, hbyomire@nda.or.ug

Figure 1. Suspected adverse drug reaction reporting form

Guidance on reporting

What to report

Report all suspected adverse drug reactions/events both serious and those that are not serious.
Report any adverse reaction even if you are not certain the product caused the vent. A reaction is serious when the patient outcome:

- *Is fatal*
- *Is life-threatening*
- *Is permanently/Significantly disabling*
- *Requires or prolongs hospitalization*
- *Causes a congenital anomaly*
- *Requires intervention to prevent permanent impairment or damage*

For reports on product quality, report complaints such as;

- Questionable stability
- Poor packaging or labeling
- Expired drugs
- Suspected contamination
- Defective components
- Therapeutic failures

When to report

Report the event soon after it occurs.

Who is to report

- All Healthcare Providers e.g. Doctors, Dentists, Pharmacists, Midwives, Nurses and Allied Health Professionals in Uganda should report as part of their professional responsibility report any suspected adverse drug reactions.

Whre to report

- Reports should be sent to the National Pharmacovigilance Centre at the National Drug Authority Secretariat.
- Reports can also be sent to the Regional Centres in Regional Referral Hospitals.
- NDA Regional offices.

How to report

- Fill in the sections that apply to your report.
- State date of administration for the suspected drug and the date when the suspected reaction occurred are mandatory.

Detection of Adverse Drug Reactions in a Patient

Follow the steps below;

- Take proper history and conduct proper examination of the patient.
- Ensure that the medicine ordered is the medicine recieved and actually taken by the patient at the dose advised.
- Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient.
- Determine the time interval between the beginning of drug treatment and the onset of the event.
- Evaluate the suspected ADR after discontinuing drugs or reducing the dose and monitor the patient's status (De-challenge). If appropriate, restart the drug treatment and monitor recurrence of any adverse events (Re-challenge).
- Analyse the alternative causes (other than the drug) that could on their own have caused the reaction.
- Use relevant up-to date literature and personal experience and their ADRs and verify if there are previous conclusive reports on this reatcion.

Please note that submission of a report doesn't imply that the health worker or the product caused or contributed to the adverse event.

Address:
Executive Secretary/Registrar
National Drug Authority
Plot 66 - 48 Lumumba Avenue
P.O. box 23096, Kampala
Tel: 255 665/347 391 - Direct line: 0414-344 052
E-mail: ndaug@nda.or.ug/druginfo@nda.or.ug

Safe Drugs Save Lives

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

A. PATIENT DETAILS

Patient Name(s)		Sex: M/F*
Age at time of onset(yrs)*	Health Facility	Last Menstrual Period
Weight (Kgs)	District	Trimester (if pregnant)

B. SUSPECTED DRUG(S) DETAILS

Generic Name*	Brand Name	Dose, Route Frequency	Date* started	Date stopped	Prescribed for	Expiry date	Batch No.

C. SUSPECTED REACTIONS

Please describe the reaction as observed and any treatment given to manage the reaction

Outcome

Recovered ☐ Recovering ☐ Continuing ☐ Death Due to Reaction ☐

Date Reaction Started*	Date Reaction Stopped	Date of Notification

SERIOUSNESS OF THE REACTION

Patient Died ☐ Prolonged inpatient Hospitalization ☐ Involved Disability ☐ Life Threatening ☐

Congenital abnormality ☐

D. CONCOMITANT DRUGS

Please give information on the drug(s) the patient has been taking together with the suspected drug including those taken for chronic diseases (include self medication and herbal preparations)

Generic	Name Brand	Dosage	Date started	Date stopped	Indication (prescribe or OTC)

Relevant laboratory tests including dates	**Additional relevant information (medical history, allergies, failure of efficacy)**

E. REPORTER'S DETAILS

Name*	Telephone and E-mail Address	Date of reporting	Designation

*Mandatory Field