STATUTORY INSTRUMENTS
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S T A T U T O R Y I N S T R U M E N T S

2014 No. 37.

THE NATIONAL DRUG POLICY AND AUTHORITY (PHARMACOVIGILANCE) REGULATIONS, 2014

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SCHEDULE

S T A T U T O R Y I N S T R U M E N T S

2014 No. 37.

The National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014.

(Made under Section 64 of the National Drug Policy and Authority Act, Cap. 206)

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 64 of the National Drug Policy and Authority Act and on the advice of the National Drug Authority, these Regulations are made this 24th day of March, 2014.

1. Title.

These Regulations may be cited as the National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014.

2. Interpretation.

In these regulation unless the context otherwise requires—

"adverse drug event" means any unwanted medical occurrence in a subject to whom a drug is administered and includes an occurrence which is not caused by or related to the drug;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function;

"counterfeit drug" means a drug which is deliberately or fraudulently mislabeled with respect to its identity, content or source;

"licensed person" means a person licensed under section 14 of the Act;

"periodic safety update report" means a report on the safety experience of a drug at defined times, after the drug is registered;

"pharmacovilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem.

3. Requirement for a pharmacovigilance system.

(1) A licensed person shall have an appropriate system for pharmacovigilance, to manage the safety of the data for the drugs for which the licensed person is responsible.

(2) The following shall have appropriate mechanism of monitoring the safety of the drugs that are handled in their day to day activities—

(a) a manufacturer or importer of drugs who is licensed to do so under the Act and regulations made under the Act;

(b) a licensed person, doctor or health professional who is involved in handling drugs intended for human use, in public health programs and programs organised and sponsored by nongovernmental organisations; and

(c) any other person as may be determined by the Authority.

(3) Where the Authority determines that a drug may not be safe to use, the Authority shall request a licensed person to submit to the Authority—

(a) a periodic safety update report; and

(b) any other reports that may be relevant to determine the safety, efficacy and quality of the drug, as the Authority may determine.

(4) A report required in subregulation (3) (a) shall be submitted using the format in the Schedule to these Regulations, for human drugs or veterinary drugs, respectively.

4. Periodic safety update reports.

(1) A licensed person shall, for the drugs handled by the licensed person, submit to the Authority—

(a) on an annual basis, a periodic safety update report of a drug that has been manufactured, sold or supplied in Uganda, as the case may be, for less than ten years;

(b) once every three years, a periodic safety update report and the efficacy profile of a drug that has been manufactured, sold or supplied in Uganda, as the case may be, for more than ten years; and

(c) any other report as the Authority may determine.

(2) Notwithstanding subregulation (1), the Authority may, where it deems necessary, at any time request a licensed person to submit a periodic safety update report or any other report as the Authority may determine.

(3) The Authority may, request a licensed person to conduct a concise critical analysis of the safety, resistance and efficacy profile of a drug and to submit the results of the analysis to the Authority, within the time specified.

5. Investigations for adverse drug event.

The Authority may conduct an investigation, with regard to a drug where—

(a) an adverse reaction is reported;

(b) it is suspected or found that a drug of the licensed person does not comply with the requirement of the Act;

(c) there is an international alert with regard to such a drug;

(d) the drug is recalled in Uganda or in any other country;

(e) there is need for additional investigations into the drug;

(f) there is need for educational initiatives to improve the safe use of the drugs;

(g) there is a change in the scheduling or manufacture of the drug to make it safer;

(h) for regulatory and health promotion interventions, as the situation may warrant, including change in supply status or withdrawal; or

(i) where the Authority for any other reason deems it fit to conduct an investigation on the drug.

6. Requirement for health care professional to report.

A health care professional shall report any serious adverse drug event that arises during the process of providing health care.

7. Reporting of counterfeit drugs.

(1) Where a drug is suspected to be a counterfeit drug, the licensed person, healthcare professional or any other person who suspects that a drug is a counterfeit drug shall report to the Authority.

(2) A person shall not deal in any drug that is confirmed to be a counterfeit drug.

(3) Where the Authority confirms that a drug is a counterfeit drug, the Authority shall confiscate the counterfeit drug.

(4) "Any other person" in sub regulation (1) includes a licensed person and a healthcare professional who is employed to handle drugs for a public health program or for a nongovernmental organization.

(5) Where the Authority determines that a drug suspected to be a counterfeit needs extra monitoring, the licensed person shall be required to submit to the Authority—

(a) reports of the drug, where the drug has obvious or perceived quality defects; and

(b) any other report which is relevant to the safety, efficacy and quality of the drug as the Authority may determine.

(6) A report submitted under this regulation shall be in a format approved by the Authority or in any other manner as may be prescribed by the Authority.

8. Investigations into a suspected counterfeit drug.

The Authority may conduct an investigation, with regard to a drug where—

(a) a report of a suspected counterfeit drug is made;

(b) there is a regional or international alert with regard to a counterfeit drug; or

(c) the Authority deems it fit to conduct an investigation on a drug.

9. Offences

Any person, who withholds safety information or tries to obstruct the Authority from getting information, commits an offence under the Act.

SCHEDULE

FORMATS.

Regulation 3(4)

Format of Report on Suspected Adverse Drug Reactions for Human Drugs

Please note that identities of the patient, reporting doctor, pharmacist, nurse and health facility are to be kept strictly confidential.

1. Details of patient

Surname:
Other names:
Age:
Sex:
Weight:
Date of LMP:
OPD No.:
Name of health facility:
District:

2. Details of the drug

State the brand and generic names of the suspected drug, indicate why the drug was prescribed or taken, state the dates of manufacture and expiry of the drug, indicate the route, state the dates when the patient started and stopped using the drug, the daily dose, diluents details, lot/batch no. and state whether the drug was prescribed or not.

3. Reaction details

Please specify and describe the details of the suspected reactions, the date the reaction started, the date of notification of the reaction and the date when the reaction stopped.

Mention any treatment that was given to the patient for the reaction. If the patient was admitted, record the duration of admission in days, the outcome of the treatment (whether the treatment is ongoing, or whether the patient recovered or died and if the patient died, indicate the date of death).

4. Other drugs used (including self medication, vaccines, herbal preparations).

Record the name of the drug, the indication, daily dose and the dates the patient started and stopped using the drug.

5. Comments.

Record any other information for example the relevant history, allergies, failure of efficacy, counterfeit, test result, follow up data of the drug or patient as the case may be.

6. Details of licensed person who submits report.

Name:
Postal address:
Designation:
Telephone:
Telephone/fax number:
Signature:
Date:

Regulation 3 (4)

Format of Report on Suspected Adverse Drug Reactions for Veterinary Drugs

Please note that identities of the owner of the animal, veterinary surgeon or Para-veterinarian who makes the report and the animal clinic are to be kept strictly confidential

1. Details of owner of animal

Name:
Address:
Telephone number:
Email address:
Village:
Sub-county:
District:

2. Details of animal

Breed:
Sex:
Age:
Weight:
Productive status:
Reproductive status:
Name and identification number of animal:
Species:

3. Details of suspected drug

Record both the brand and generic names of the suspected drug, the condition treated, the dates of manufacture and expiry of the drug, the route, the dates when the animal started and stopped taking the drug, the dosage and batch number.

4. Drug administered by (if owner is a vet professional, tick both title and owner boxes)

Veterinary doctor
Owner
Para-veterinarian
Others (specify)

5. Reaction Details

Please specify the details of the suspected reactions and indicate whether the reaction was immediate or delayed.

6. Other drugs used within seven days (including drugs administered by animal owner, vaccines, herbal preparations)

Record the name of the drug, the indication, the daily dose and the date the animal started stopped taking the drug.

7. Comments

Record any other information for example the relevant history, allergies, failure of efficacy, counterfeit, test result and follow up data.

8. Details of the licensed person who submits report

Name:
Postal address:
Designation:
Telephone and fax numbers:
Signature:
Date:

RUHAKANA RUGUNDA (DR.),
Minister of Health.