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

2021 No. 41.

The National Drug Policy and Authority (Pharmacovigilance) (Amendment) Regulations, 2021.

(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 16th day of June, 2021.

1. Title.

These Regulations may be cited as the National Drug Policy and Authority (Pharmacovigilance) (Amendment) Regulations, 2021.

2. Amendment of S.I 37 of 2014

The National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014, in these Regulations referred to as the principal Regulations, are amended in regulation 2 is amended—

(a) by inserting the following definitions appropriately—

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

"**substandard drug**" means a drug which does not meet the quality specifications approved by the Authority;" and

(b) by replacing the definition of "Pharmacovilance" with the following—

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

3. Amendment of Regulation 3

Regulation 3 of the principal Regulations is amended in subregulation (2) by substituting for paragraph (b), the following—

"(b) a licensed person, a holder of a certificate of registration, doctor or health professional who is involved in handling drugs intended for human or animal use, in public health programs and programs organized and sponsored by non-government organisations; and".

4. Amendment of regulation 4

Regulation 4 of the principal Regulations is amended by substituting for the regulation, with the following—

"**4. Periodic safety update report, periodic benefit risk evaluation report and risk management plan.**

(1) A person issued with a certificate of registration for a product, shall submit to the Authority a periodic safety update report or periodic benefit risk evaluation report for the product by the person—

(a) at least every six (6) months during the first 2 years following the initial registration

(b) once every two (2) years after the period stated in a) above

(c) every three years after the period stated in b) above;

(d) at any time where the Authority deems it necessary.

(2) A licensed person issued with an import permit for unregistered drugs shall submit to the Authority a periodic safety update report and periodic benefit risk evaluation report for the drugs handled by the licensed person on an annual basis.

(3) A periodic benefit risk evaluation report shall contain a comprehensive, concise, and critical analysis of product's known or emerging important risks including the following—

(a) summary of relevant new safety information that could have an impact on the benefit-risk profile of the product;

(b) summary of any important new efficacy or effectiveness information that has become available during the reporting interval;

(c) assessment of whether the information obtained by the licensed person or manufacturer during the reporting interval is in accord with previous knowledge of the product's benefit and risk profile;

(d) integrated risk- benefit evaluation for approved indications in case a new safety information has emerged;

(e) recommended action to optimize the benefit-risk profile.

(4) A person issued with a certificate of registration or authorization to import drugs, manufacturer or licenced person shall in addition to a periodic safety update report or periodic benefit risk evaluation report, for the drugs specified by the Authority, submit to the Authority, a risk management plan of the drug that is proposed to be manufactured, sold or supplied in Uganda focused on the safety concerns.

(5) The Risk Management Plan required under subregulation 4, shall contain the following information—

(a) the product overview;

(b) the safety specification;

(c) the epidemiology of the indication(s) and the target population;

(d) the non-clinical part of the safety specification;

(e) the clinical trial exposure of the product;

(f) the populations which are not studied in clinical trials;

(g) any post-authorization experience;

(h) any additional requirements for the safety specification;

(i) the identified and potential risks;

(j) a summary of the safety concerns;

(k) a pharmacovigilance plan including post-authorisation safety studies;

(l) plans for post-authorisation efficacy studies;

(m) the risk minimization measures including evaluation of the effectiveness of risk minimization activities; and

(n) a summary of the risk management plan.

(6) A risk management plan shall be submitted—

(a) at the time of registration of the drug where applicable.

(b) upon identification of safety data or risk, an updated Risk Management Plan of the drug that has been manufactured, sold or supplied in Uganda, as the case may be, for more than ten years.

(c) where the Authority deems fit."

6. Amendment of Regulation 6

Regulation 6 is amended by substituting for the regulation the following—

"6. Requirement for health care professional to report.

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

7. Amendment of regulation 7

Regulation 7 is amended by substituting for the regulation the following—

"Reporting of falsified or substandard drugs.

(1) A person shall not deal in any drug that is confirmed to be a falsified or substandard drug.

(2) Where a drug is suspected to be falsified or substandard, the licensed person, healthcare professional or any other person who suspects that a drug is falsified or substandard, shall make a report on the drug to the Authority.

(3) "Any other person" in sub regulation (2) includes a licensed person and a healthcare professional who is employed to handle drugs for a public health program or for a nongovernmental organization.

(4) The Authority shall conduct an investigation on a specific drug and confiscate a drug under investigation where a report is made in subregulation (2).

(5) The Authority shall during an investigation of the drug in subregulation (4), stop further supply of the drug.

(6) A person licensed to import or manufacture, may be required by the Authority to monitor the safety of products and where a product is suspected to be substandard or falsified, make reports to the Authority.

(7) 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. Amendment of Regulation 8

Regulation 8 is amended by substituting for the provision as follows—

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

(a) a report of a suspected substandard or falsified drug is made

(b) there is a regional or international alert with regard to a substandard or falsified; or

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

HON. DR. ACENG JANE RUTH OCERO,
Minister for Health.