MINISTRY OF MEDICAL SERVICES **MINISTRY OF PUBLIC HEALTH AND SANITATION**

PHARMACY AND POISONS BOARD

MEDICINE SAFETY "PHARMACOVIGILANCE" FACT SHEET

What is medicine safety?

Medicine safety, also referred to as Pharmacovigilance refers to the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines. It aims at identifying new information about hazards, and preventing harm to patients.

What is an Adverse Drug Reaction?

The World Health Organization defines an adverse drug reaction (ADR) as "A response to a drug which is noxious and unintended, and which occurs at doses normally used or tested in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function".

Simply put, when the doctor prescribes you medicines, he expects the desirable effects of them. The undesired effects of the medicines is the ADR or, commonly known as "side effects".

An adverse drug reaction is considered to be serious when it is suspected of causing death, poses danger to life, results in admission to hospital, prolongs hospitalization, leads to absence from productive activity, increased investigational or treatment costs, or birth defects.

Age, gender, previous history of allergy or reaction, race and genetic factors, multiple medicine therapy and presence of concomitant disease processes may predispose one to adverse effects.

Why monitor adverse drug reactions?

Before registration and marketing of a medicine, its safety and efficacy experience is based primarily on clinical trials. Some important adverse reactions may not be detected early or may even be rare. In addition, controlled conditions in clinical trials may differ from real practice for instance when patients have taken multiple medicines for various ailments. A continuous post-marketing monitoring system is therefore essential.

What is post-market surveillance?

Post-market surveillance (PMS) ensures that medicines meet the required standards in terms of quality, safety and efficacy both at and after registration.

What is the scope of pharmacovigilance?

- Substandard and counterfeit medicines
- Product development
- Medication error reporting
- Adverse interactions of medicines with chemicals, other medicines, and food reports
- Assessment of drug-related mortality
- Abuse and misuse of medicines reports
- Efficacy monitoring
- Off-label use of medicines
- Case reports of acute and chronic poisoning

What is a poor quality medicinal product?

This refers to any medicinal product that does not meet the required quality standards in terms of physical appearance, level of active ingredients, packaging, labeling and others. This includes:

- Colour change
- Separating of components
- Powdering / crumbling
- Caking
- Moulding
- Change of colour / odour
- Mislabeling
- Incomplete pack
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging / poor labeling
- Therapeutic failures (lack of efficacy)
- Receiving expired medicines

What are counterfeit medicines?

WHO defines a counterfeit medicine as “one which is deliberately and fraudulently mis-labelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging”.

Simply put, it is faking a medicine for one that it truly is not. Counterfeit medicines kill!

How are adverse drug reactions, poor quality medicines, sub-standard medicines and counterfeit medicines monitored after a medicine has been marketed?

Reports are voluntarily submitted by health professionals and consumers and coordinated by the Division of Medicines Information, Department of Pharmacovigilance (PPB).

Reports on **adverse reaction to a medicine** should be made using a "yellow form" (Form for Reporting Suspected Adverse Drug Reactions) <http://www.pharmacyboardkenya.org/assets/files/Suspected ADR Notification Form.pdf>.

Reports on **poor quality medicine**, **sub-standard medicine** or **counterfeit medicine**, should be made using a "pink form" (Form for Reporting Poor Quality Medicinal Products)
<http://www.pharmacyboardkenya.org/assets/files/Form for Reporting Poor Quality Medicinal Products.pdf>

The reporter will also be required to send the appropriate amount of sample of the poor quality medicinal product to PPB for further evaluation. All reports are individually reviewed by an Expert Safety Review Panel (ESRP) comprising of trained medical and para-medical professional staff.

What happens to an adverse reaction report?

When reports are received, they are reviewed and entered into the national adverse drug reaction database. The data is then analyzed to identify safety signals. A signal is a preliminary indication of a medicine-related safety issue and by itself does not indicate a causal association. A detailed evaluation is undertaken to establish whether a true causal association exists between the medicine and the adverse drug reaction.

Are there any limitations of adverse drug reaction information?

Under-reporting and lack of reliable data on the number of people exposed may limit epidemiological analyses of the data. The information gained from an adverse drug reaction report may also be incomplete, making it difficult to extrapolate to a national level.

What actions can be taken by the Pharmacy and Poisons Board on establishment of a true causal association?

Possible regulatory actions vary from continuing observation to cancelling the registration of the drug. Other possibilities include:

- Additional investigations into the use of the medicine in Kenya
- Informing health care professionals and consumers about the risks of medicines
- Re-assessment of the benefit-risk profile of a medicine in Kenya
- Directing product labeling changes (such as the addition of contraindications, warnings and boxed warnings, precautions and adverse reaction information to the Product Information and Consumer Information documents)
- Change in the schedule of the medicine
- Requesting post-marketing studies
- Other regulatory and health promotion interventions as the situation may warrant including withdrawal and recall of the medicine.

Confidentiality All reports are handled in a confidential manner and do not bear details of reporters when the details of a specific event are communicated. Reports do not constitute an admission that the reporter or any other person contributed to or caused the event in any way.

How do I contact the Pharmacy and Poisons Board?

Physical location:	ALONG LENANA ROAD, NAIROBI.
	BETWEEN NATIONAL IRRIGATION BOARD AND LENANA CONFERENCE CENTRE, OPPOSITE DEPARTMENT OF DEFENCE (D.O.D) AND RUSSIAN EMBASSY
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Web site:	www.pharmacyboardkenya.org
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