Pharmacovigilance overview in Kenya

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Global Antibiotic Resistance Partnership

CDDEP THE CENTER FOR Disease Dynamics, Economics & Policy
WASHINGTON DC • NEW DELHI

Outline

- Introduction
- Whats is Pharmacovigilance
- Pharmacovigilance in Kenya-where we are
- Some regulatory aspects in Kenya arising from pharmacovigilance
- Way forward .

Pharmacy and Poisons Board

The PPB is the Drug Regulatory Authority of the Ministry of Medical Services, Kenya.

It was established in 1957 under the Pharmacy and Poisons Act- Cap 244 of the Laws of Kenya, with the mandate:

"to make better provision for the practice and profession of pharmacy and the trade in pharmaceutical products."

Pharmacovigilance in its broadest terms

- Monitoring medicines to determine unrecognised adverse effects or changes in the patterns of their adverse effects

-yellow cards, signals from clinical trials

- Continuously assessing the risks and benefits of medicines, taking action if necessary to improve their safe use

-adding information to the information leaflet or packaging, restricting use of a drug, withdrawing a drug

Post Market Surveillance

- **Post-market surveillance** ensures that, even after registration, drugs continue to meet the required standards whilst in the market.

  - **Quality……Safety……Efficacy**

What is an Adverse Drug Reaction?

The WHO describes an ADR as …

‘ A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnoses or therapy of disease, or for the modification of physiological function**.** ’

Pharmacovigilance in Kenya

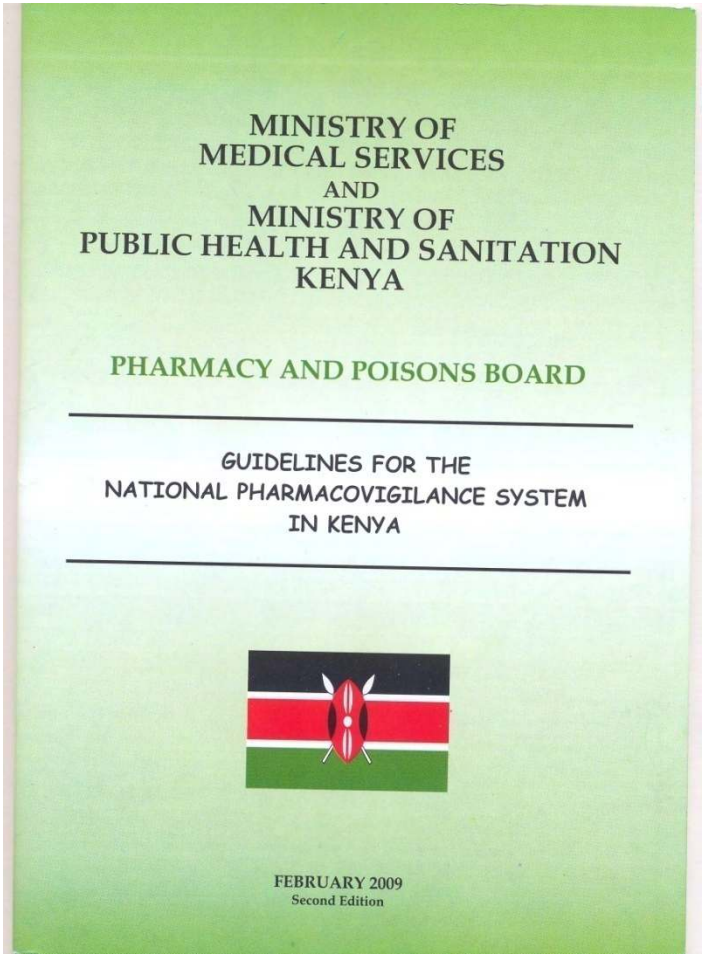
- Guidelines for the National PV System in Kenya developed
- Tools developed:
  - ✓ *Suspected ADR Reporting Form*
  - ✓ *Alert Card*
  - ✓ *Form for Reporting Poor Quality Medicinal Products*
- 'Field testing' of PV guidelines and tools completed
- Training material developed: training curricula, guides and manuals

Pharmacovigilance in Kenya

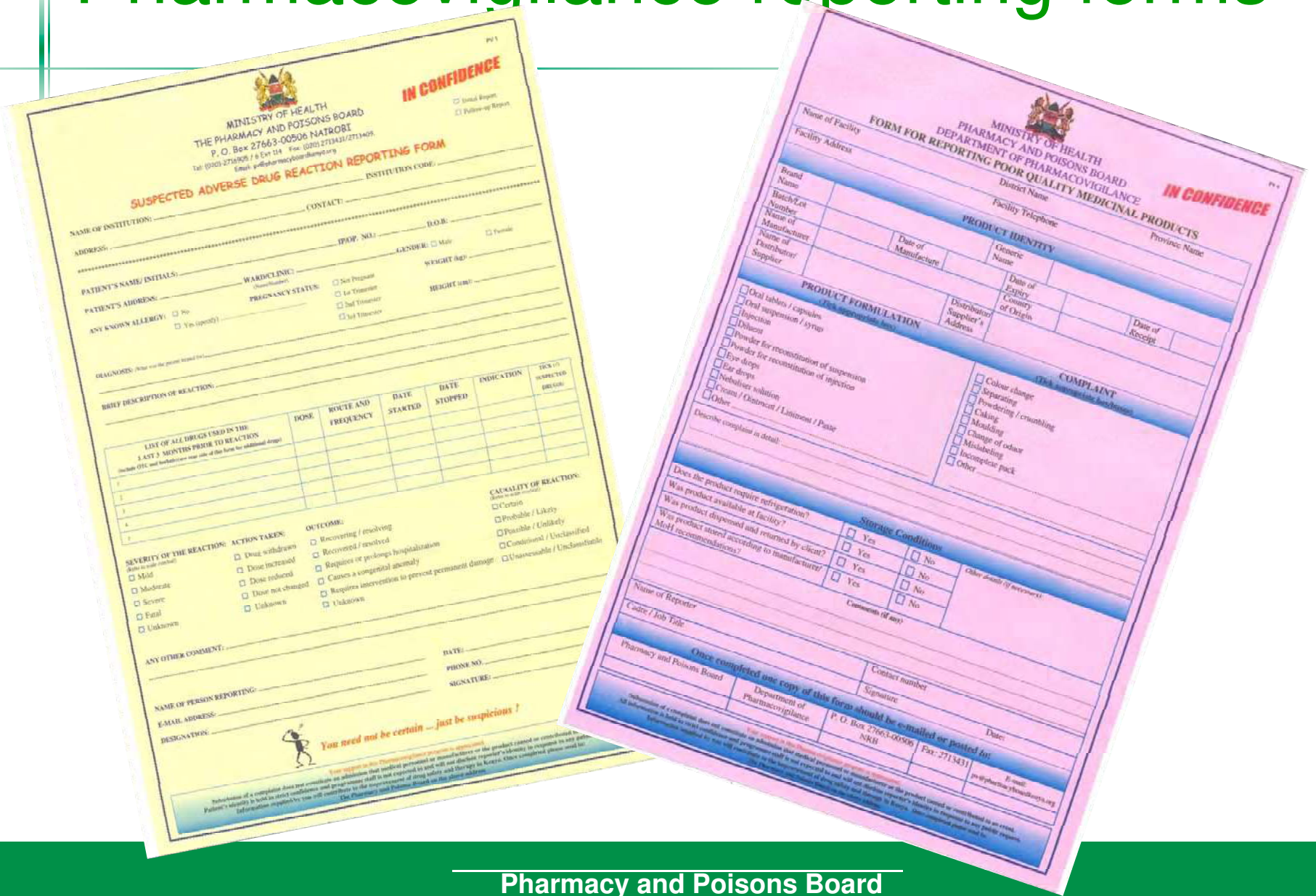
- Formal launch of the National Pharmacovigilance System in Kenya 9th June 2009, Nairobi
  - Representatives from both MoPHS and MoMS Hq
  - Provincial representatives of both
  - Stakeholders
- 1st and 2nd PV Facilitators training (22nd-26th June and 13th - 17th July 2009)
  - 4 provinces
  - Clinicians, clinical officers, nurses, pharmacists, pharm-techs
- Preparing for roll-out

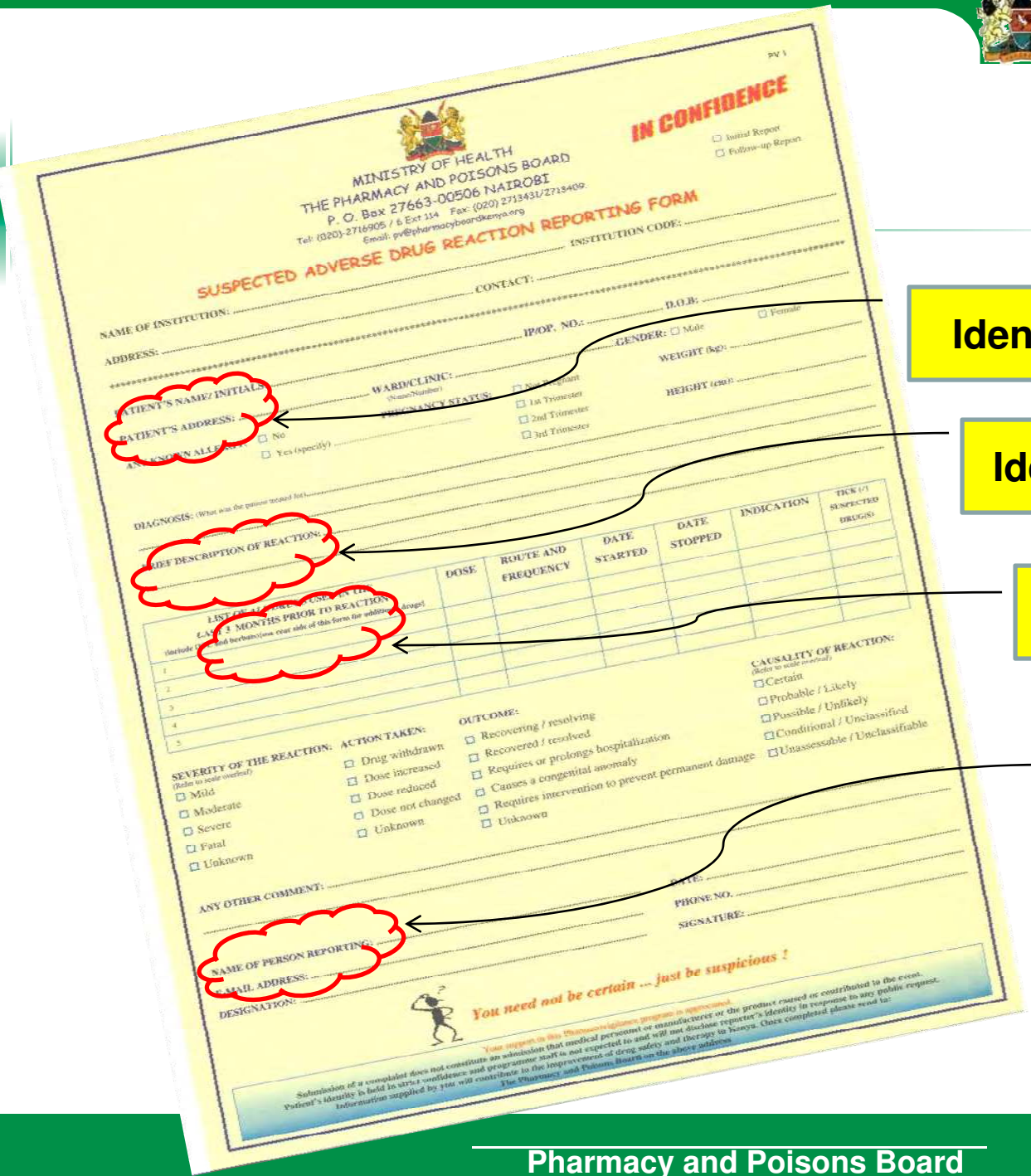
Pharmacovigilance Reporting Tools

Guidelines for the National Pharmacovigilance System in Kenya



Pharmacovigilance reporting forms





Identifiable patient

Identifiable reaction

Identifiable drug

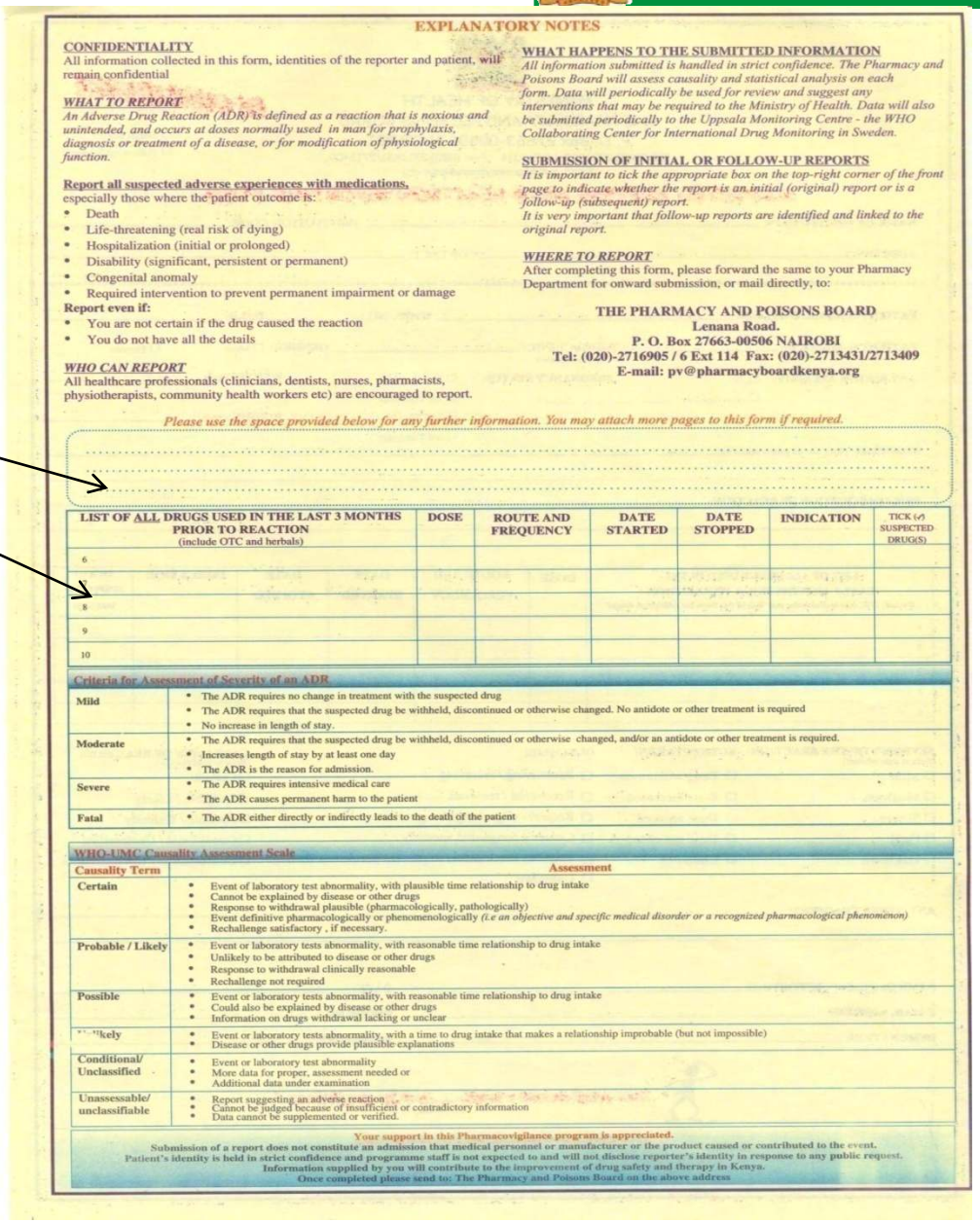
Identifiable reporter

Rear view

More space to fill in more information and list more drugs

Severity assessment scale

Causality assessment scale



EXPLANATORY NOTES

CONFIDENTIALITY
All information collected in this form, identities of the reporter and patient, will remain confidential

WHAT TO REPORT
An Adverse Drug Reaction (ADR) is defined as a reaction that is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or treatment of a disease, or for modification of physiological function.

Report all suspected adverse experiences with medications, especially those where the patient outcome is:

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You are not certain if the drug caused the reaction
- You do not have all the details

WHO CAN REPORT
All healthcare professionals (clinicians, dentists, nurses, pharmacists, physiotherapists, community health workers etc) are encouraged to report.

WHAT HAPPENS TO THE SUBMITTED INFORMATION
All information submitted is handled in strict confidence. The Pharmacy and Poisons Board will assess causality and statistical analysis on each form. Data will periodically be used for review and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uppsala Monitoring Centre - the WHO Collaborating Center for International Drug Monitoring in Sweden.

SUBMISSION OF INITIAL OR FOLLOW-UP REPORTS
It is important to tick the appropriate box on the top-right corner of the front page to indicate whether the report is an initial (original) report or is a follow-up (subsequent) report.
It is very important that follow-up reports are identified and linked to the original report.

WHERE TO REPORT
After completing this form, please forward the same to your Pharmacy Department for onward submission, or mail directly, to:

THE PHARMACY AND POISONS BOARD
Lenana Road.
P. O. Box 27663-00506 NAIROBI
Tel: (020)-2716905 / 6 Ext 114 Fax: (020)-2713431/2713409
E-mail: pv@pharmacyboardkenya.org

Please use the space provided below for any further information. You may attach more pages to this form if required.

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (✓) SUSPECTED DRUG(S)
6						
8						
9						
10						

Criteria for Assessment of Severity of an ADR

Mild	• The ADR requires no change in treatment with the suspected drug • The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required • No increase in length of stay.
Moderate	• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required. • Increases length of stay by at least one day • The ADR is the reason for admission.
Severe	• The ADR requires intensive medical care • The ADR causes permanent harm to the patient
Fatal	• The ADR either directly or indirectly leads to the death of the patient

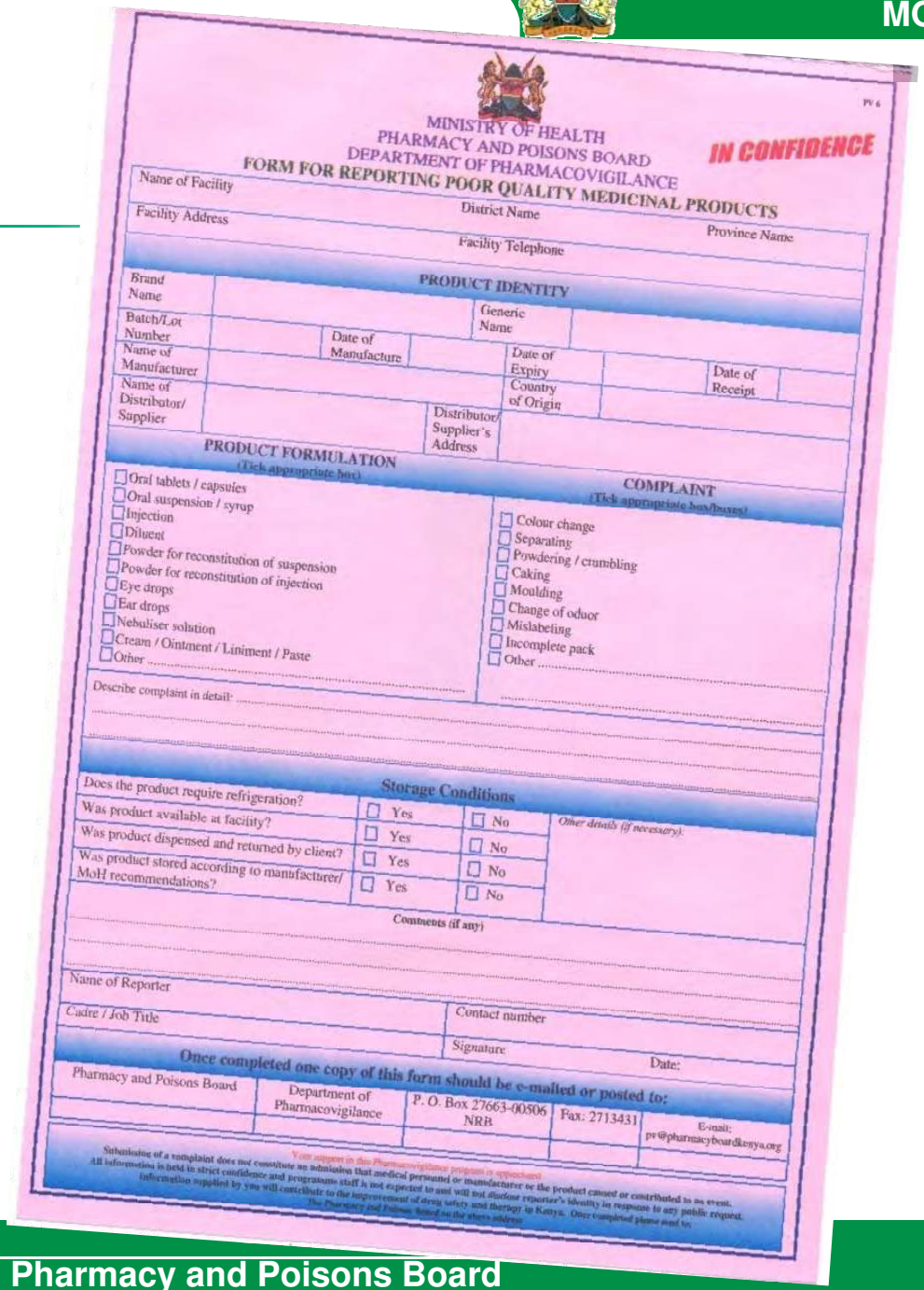
WHO-UMC Causality Assessment Scale

Causality Term	Assessment
Certain	• Event of laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically *(i.e an objective and specific medical disorder or a recognized pharmacological phenomenon)* • Rechallenge satisfactory , if necessary.
Probable / Likely	• Event or laboratory tests abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory tests abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drugs withdrawal lacking or unclear
"kely	• Event or laboratory tests abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper, assessment needed or • Additional data under examination
Unassessable/ unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because of insufficient or contradictory information • Data cannot be supplemented or verified.

Your support in this Pharmacovigilance program is appreciated.
Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya.
Once completed please send to: The Pharmacy and Poisons Board on the above address

PV 6 (PINK FORM)

FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS



PV 6

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
DEPARTMENT OF PHARMACOVIGILANCE

IN CONFIDENCE

FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS

Name of Facility | District Name | Province Name

Facility Address | Facility Telephone

PRODUCT IDENTITY

Brand Name | Generic Name

Batch/Lot Number | Date of Manufacture | Date of Expiry | Date of Receipt

Name of Manufacturer | Country of Origin

Name of Distributor/ Supplier | Distributor/ Supplier's Address

PRODUCT FORMULATION (Tick appropriate box)

- ☐ Oral tablets / capsules
- ☐ Oral suspension / syrup
- ☐ Injection
- ☐ Diluent
- ☐ Powder for reconstitution of suspension
- ☐ Powder for reconstitution of injection
- ☐ Eye drops
- ☐ Ear drops
- ☐ Nebuliser solution
- ☐ Cream / Ointment / Liniment / Paste
- ☐ Other .....

COMPLAINT (Tick appropriate box/boxes)

- ☐ Colour change
- ☐ Separating
- ☐ Powdering / crumbling
- ☐ Caking
- ☐ Moulding
- ☐ Change of oduor
- ☐ Mislabeling
- ☐ Incomplete pack
- ☐ Other .....

Describe complaint in detail: .....

Storage Conditions

Does the product require refrigeration?	☐ Yes	☐ No	Other details (if necessary):
Was product available at facility?	☐ Yes	☐ No	
Was product dispensed and returned by client?	☐ Yes	☐ No	
Was product stored according to manufacturer/ MoH recommendations?	☐ Yes	☐ No	

Comments (if any)

Name of Reporter

Cadre / Job Title | Contact number

Signature | Date:

Once completed one copy of this form should be e-mailed or posted to:

Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB	Fax: 2713431	E-mail: pv@pharmacyboardkenya.org

Your support in this Pharmacovigilance program is appreciated

Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please mail to: The Pharmacy and Poisons Board at the above address