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GUIDANCE MANUAL FOR

PHARMACOVIGILANCE FOCAL POINTS IN NIGERIAN HEALTHCARE FACILITIES

Effective Date: 10-10-2024 Doc. Ref. No. PV- GDL-026-00

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Table of Contents

1. Objective

This manual aims to support pharmacovigilance practice in Nigerian healthcare facilities and ensure its consistency with international regulations, especially the requirements of the World Health Organization.

2. Scope:

- This manual is concerned with the pharmacovigilance system and processes within healthcare facilities but not the technical knowledge of pharmacovigilance
- For more details about pharmacovigilance, please refer to the official website of the National Agency for Food Drug Administration and Control for the Guidelines for detecting and reporting adverse reactions to Pharmaceutical products and Medical devices.

3. Pharmacovigilance role in patient safety

- The pharmacovigilance is one of the major pillars for patient and medication safety in healthcare facilities
- It falls on the shoulders of the healthcare facility management to ensure that all healthcare professionals within the facility are familiar with the principles and concepts of pharmacovigilance and reporting mechanisms. The management should also work towards increasing the awareness of medicine safety, as well as providing the necessary support to the pharmacovigilance focal points to carry out the tasks of monitoring and following up on adverse events within the healthcare facility.

4. Nomination and allocation of pharmacovigilance focal person

1) The hospital management shall allocate a qualified pharmacist or more to assume the pharmacovigilance responsibilities within the healthcare facility. It's preferred for the pharmacovigilance team to include two pharmacists, one as the primary focal person and supervisor of the pharmacovigilance work within the facility and the other shall work as a deputy and a team member, in accordance with the recruitment plan, workload and the size of the health facility.

2) The basic qualifications to be taken into consideration when selecting the focal points:

   - The preferred candidates should have technical competency, clinical pharmacy experience, and a pharmacovigilance specialist qualification from the West African Postgraduate College of Pharmacists or an advanced degree in pharmacovigilance (MSc or PhD).

   - Good knowledge of the programs (PowerPoint, Excel, and Word)

   - The focal points need to receive qualifying training in pharmacovigilance.

   - Effective communication skills.

   - Commitment and discipline.

3) An appointment letter shall be issued to designate a focal person in the healthcare institution, that shall be published via the various means of communication among the staff within the facility.

4) The hospital management shall ensure that the focal person is well known to the staff, with a clear and easy route of communication. The focal point's contact details (phone number, WhatsApp groups… etc.) should be published within the facility and well known among the staff members.

5) An announcement about pharmacovigilance in English targeting the healthcare facility could be placed in the drug dispensing area. The announcement shall include: (A simple definition of pharmacovigilance, what, when, and how to report adverse drug events).

6) The job performance of the focal person shall be evaluated periodically by the central pharmacovigilance coordinator (if any) or the facility's management. The evaluation result shall be documented.

7) The focal person needs:

   - Computer connected to the Internet;

   - Office; and

   - Printer + papers.

5. Role of the pharmacovigilance focal person in healthcare facilities

5.1. Role of focal person in preparing the PV policy and the standard operating procedures (SOPs)

The focal points for pharmacovigilance shall formulate the pharmacovigilance policy and the pharmacovigilance the standard operating procedures (SOPs) within the healthcare facility. Ideally, the policy shall contain the following:

- The purpose
- Related pharmacovigilance definitions
- The scope
- The mechanism of detection and reporting of adverse events within the facility.
- Who can report?
- When to report?
- Adverse Events cases validation
- How to prevent preventable adverse events and implement corrective measures when needed.
- Follow up mechanism with healthcare professionals to complete the information of the reported cases when needed.
- A flow chart showing the steps from detecting adverse events to sending report to the national pharmacovigilance database in the National Agency for Food Drug Administration and Control. **(See annex (1))**
- Mechanism for classifying the adverse events into serious and non-serious and how to prioritize the work accordingly.
- The reporting timelines
- How to share the feedback and comments from the National Agency for Food Drug Administration and Control to the reporters and other healthcare professionals.
- The policy effective date update date.
- References and resources.
- Appendixes: Contain the forms to work with

5.2. The pharmacovigilance focal person's role in the Drug Therapeutic Committee

- The pharmacovigilance focal person or a representative shall attend the drug committee and discuss the topics related to pharmacovigilance and drug safety.
- Documenting the subject and the resulting recommendations and outcome in the committee meeting minutes.
- A clear communication channel shall be present between the focal person and the Drug Committee.
- The previous articles shall be explicitly stated in the committee's terms of reference or the pharmacovigilance SOPs.
- Documentation of the subject related to pharmacovigilance and drug safety presented to the committee and decisions taken by the Drug Committee. **(See template (2))**

5.3. The role of the pharmacovigilance focal person as a contact point inside and outside the healthcare facility

- The focal person shall receive all reports related to drug and patient safety from various sources (patients and healthcare professionals) within the healthcare facility.
- The focal person shall encourage and motivate patients and healthcare professionals to report drug and patient safety problems.
- The pharmacovigilance focal points shall work to clarify the pharmacovigilance scope within the health facility, which includes but is not limited to, suspicion of adverse events, quality issues associated with adverse events, lack of drug effect, and medication error associated with adverse events.
- Yellow forms shall be popularized among healthcare professionals and kept after filling them out.
- The focal person shall acknowledge the reporter and work to overcome obstacles or fears that would limit reporting.
- The focal point, in addition to the drug information center (if present), can answer patients' and healthcare professionals' safety and medicine-related inquiries.
- The qualified person for pharmacovigilance shall represent the drug and patient safety file within the Drug and Medicine Committee as well as he shall publish the procedures and activities approved by the committee.

- The qualified person for pharmacovigilance shall deliver the feedback/ comments (including the evaluation of causality) related to the report from the National Agency for Food Drug Administration and Control to the reporter.
- The focal person shall disseminate NAFDAC's Newsletters, Safety alerts, and Direct Healthcare professional communications among healthcare professionals within the healthcare facility.
- The pharmacovigilance focal person shall work to increase awareness of precautions and preventive measures to assure patient safety. This can be achieved by preparing awareness flyers and disseminating them in available communication channels inside and outside the healthcare facility (WhatsApp and Facebook pages).
- If the need arises to carry out investigations, the National Agency for Food Drug Administration and Control may request the assistance of the healthcare facility focal person in information collection accurately and comprehensively after the coordination with the central coordinator (if present).
- The pharmacovigilance focal person shall participate in scientific conferences and publish what he deems appropriate based on the healthcare facility's experience in the pharmacovigilance field.

5.4. Role of Pharmacovigilance focal person in the training of Healthcare professionals

5.4.1. The focal person training:

- The pharmacovigilance focal person shall receive adequate training from the National Pharmacovigilance Center - NAFDAC.
- The pharmacovigilance focal person should participate (if feasible) in the events and training offered by the National Agency for Food Drug Administration and Control.
- The pharmacovigilance focal person shall document the training received and events attended to keep up with the new developments in the pharmacovigilance field.

5.4.2. Pharmacovigilance focal person role in the training of staff members in healthcare facilities:

- The health facility's training plan shall include training on pharmacovigilance concepts and reporting mechanisms within the facility.

- The pharmacovigilance focal person shall prepare an annual training plan targeting all the staff in the healthcare facility. **(See template (3))**.
- All training shall include the basic concepts of pharmacovigilance and reporting mechanisms within the health facility, in addition to other topics that health care professionals may need.
- Training on pharmacovigilance concepts shall be included in the new employees' training program/induction training and is provided within 1 month of employment.
- The pharmacovigilance focal person shall work in cooperation with the pharmacy team and the health facility management to establish the activities and events that address pharmacovigilance topics and measures that enhance patient safety.
- It's recommended for the healthcare facility to participate in events and activities directed to the community in general (for example: The Patient Safety Week, … etc.).
- The pharmacovigilance focal person shall document all training activities through attendance sheets and photographs and retain them. It is preferable to conduct a pre- and post-training evaluation/test and document its results.

5.5. Follow-up and documentation mechanisms

5.5.1. Follow up with the reporter:

- The pharmacovigilance focal person shall follow up with the reporter to complete the case's important information.
- The pharmacovigilance focal person shall update the case reports with the additional obtained information.
- The pharmacovigilance focal person shall follow up with the central coordinator (if present) concerning reported cases.
- The pharmacovigilance focal person shall provide the initial causality assessment to the reporter.

5.5.2. Comprehensive follow-up of progress in pharmacovigilance in the healthcare facility:

- The pharmacovigilance focal person shall create a tracker -an Excel sheet- for follow-up of reported cases in the healthcare facility. **(See template (4))**.
- The tracker shall contain the following:

- The Case code in the healthcare facility **(See template (5))**.
- The case ID is the national adverse events database of the National Pharmacovigilance Center
- The reporter.
- Date of report
- Report type (adverse event, or quality issue, …etc.).
- Report seriousness
- The case narrative (complete sequence and context of the adverse effect).
- The feedback/ comments on the case report including the causality assessment.

5.5.3. The importance of documentation:

- In general, it is necessary and fundamental in the pharmacovigilance policy to document all pharmacovigilance-related details, procedures, activities, and events.
- The pharmacovigilance focal shall monitor and document how the pharmacovigilance activity participates in rationalizing the pharmaceutical practices in the healthcare facility.

5.6. <u>The Role of Pharmacovigilance focal person in data analysis</u>

- It is recommended that the pharmacovigilance focal person conduct an initial analysis of the reported cases at the facility level using the available files and template to answer the following questions:
  - Number of serious cases reported monthly and annually.
  - Number and classification of reports submitted monthly and annually.
  - Number of reports that have already been sent to the national database of pharmacovigilance.
  - Number of reports that have not been sent and the reasons for that.

- Number of communications with the National Pharmacovigilance Center and the used mechanisms.

- The number of inquiries received regarding the safety of the medicine and patient monthly and annually.

- The pattern/trends of recurring problems, analysis of their causes, and the possibility for prevention.

- The pharmacovigilance focal points shall review the results and proposals produced by this analysis of collected data and shall present those during the Drug Committee meetings periodically or upon request.

- Proposing prevention and corrective measures for problems raised to the Drug Committee along with methods and mechanisms for implementing those measures to enhance patient safety.

6. Required documents

Accordingly, the pharmacovigilance focal person at the healthcare facility is required to have the following documents ready when required:

- pharmacovigilance focal person CV.
- The administrative decree assigning the focal person to work in pharmacovigilance.
- Certificates, training records, and evidence proving that the focal person received the required training.
- The Pharmacovigilance policy within the healthcare facility.
- A flow chart for pharmacovigilance activities in the healthcare facility.
- Keeping/archiving the yellow cards after filling them out.
- The tracker (Excel) for tracking reports at their various phases.
- The terms of reference of the Drug Committee.

- Meeting Minutes of Drug Committee meetings that discussed medicine safety in the healthcare facility.
- Health facility's pharmacovigilance training plan.
- The new employees' training program/induction training.
- Awareness flyers.
- A combined file of the inquiries received and answered by the focal person at the healthcare facility. **(See template (6))**
- Training records/ list of attendees and evidence of training plan implementation in a combined file showing the trainees and their specializations. **(See template (7)).**
- Photographs documenting activities and events.

References:

1. WHO: Interim manual for the performance evaluation of regulatory authorities seeking the design as WHO-listed Authorities.

2. Guidance Manual for Pharmacovigilance focal points in Healthcare facilities in the Arab Republic of Egypt (Adapted)

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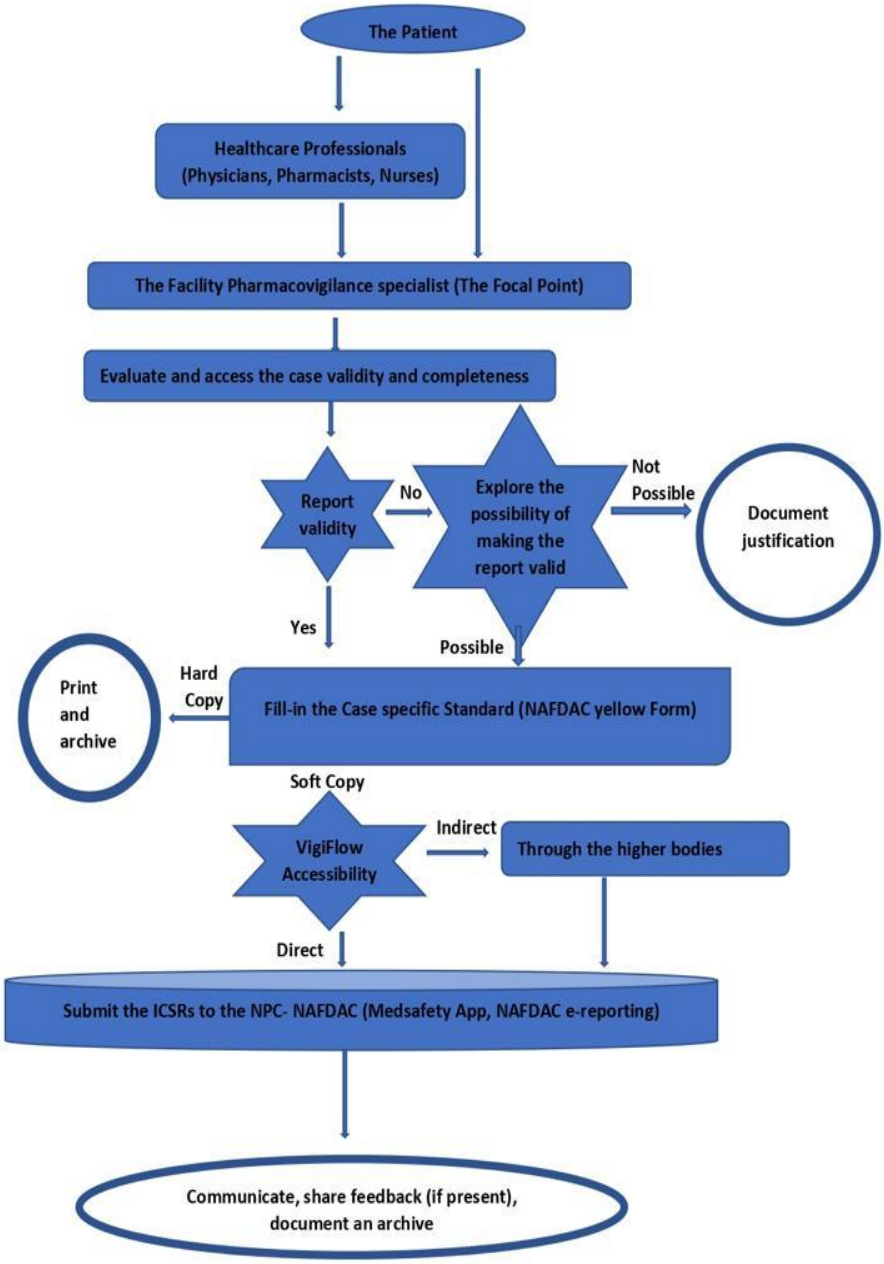
Template (1): Pharmacovigilance Process – Facility Flowchart



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Template (2) DTC pharmacovigilance-related activities documentation form:

No.	Date	Kind of activity	Purpose of activity

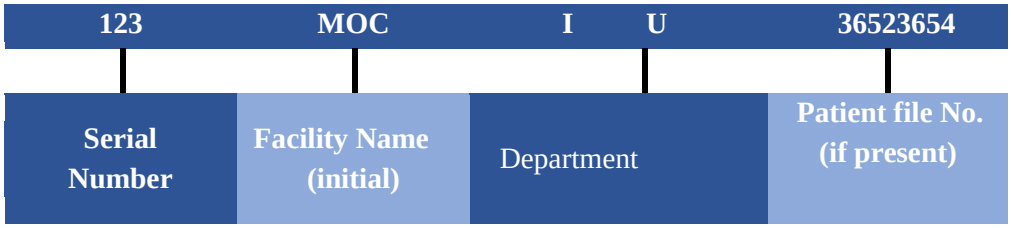
Template (3) PV Unit Annual training plan

Plan set before the beginning of the year						Filled during the proceeding and implementation of the plan		
Month	**Subject**	**Targeted audience**	**Trainer**	**Training mechanism** (lecture or awareness session)	**Expected date for implementation**	**Actual date for implementation**	**Number of attendees**	**Documentation and notes**
January	**Vigilance concepts & reporting mechanism**	**Physicians & Pharmacist**	**Focal person**	**Lecture**	**During the first week of the month**	**Jan. 3rd, 2023**	**15 Physicians & Pharmacists**	**records of attendees attached**
	Vigilance concepts & reporting mechanism	**Nurses**		**Awareness session**	**During the second week of the month**	**Jan. 9th, 2023**	**7 intensive care nurses**	**records of attendees attached**
February								
March								
April								
May								
June								
July								
September								
August								
October								
November								
December								

Template (4) Reporting Tracker:

Report internal code	Vigi. Flow ID	Initial Reporter	Date of report	Report type (ADRs/ Quality/ ME)	Report Seriousness	Case Narrative	Feedback (Yes / No)	Causality Assessment

Template (5) Health facility – Report internal code structure (guide):



Template (6): Drug information safety-related request (collective Form)

Requester (HCP or Patients)	Phone Number	Department	Date	The Question	The answer	References

Template (7): Training Tracker sheet (for HCPs)

No.	Date	Training topic	Training Purpose	Target audiences	Number of attendees	Presented by

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Template (8): The Adverse Drug Reaction Reporting Form

ANNEXURE 1	PVPMS-003-01	SERIAL NO:

National Agency for Food and Drug Administration and Control (NAFDAC), Corporate Headquarters, Plot 2032 Olusegun Obasanjo Way Wuse Zone 7, Abuja

NAFDAC
National Pharmacovigilance Centre

NAFDAC USE ONLY

A. *PATIENT INFORMATION

1. Patient's Full Name or Initials (In Confidence)

2. Age _____
Or Date of Birth (e.g. 03 May 1925) __-__-____

3. Sex
☐ Female
☐ Male

4. Weight (kg) _____

Hospital/Treatment Centre

Patient Record No _____

B. *ADVERSE EVENT

1. Describe Event

2. Seriousness of Adverse Event (Check all that apply)

☐ Death Include date (dd-mmm-yyyy) __-___-____
☐ Life threatening
☐ Hospitalization
  ☐ Initial
  ☐ Prolonged
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects
☐ Required intervention to Prevent Permanent Impairment or Disability (Devices)
☐ Others (Specify) _____

3. Outcomes

☐ Recovered fully
☐ Recovering
☐ Fatal
☐ Unknown
☐ Others (Specify) _____

4. Onset Date of Event (dd-mmm-yyyy) __-___-____

5. Stop Date of Event (dd-mmm-yyyy) __-___-____

C. *SUSPECTED DRUG (Including Biologicals, Traditional/Herbal Medicines & Cosmetics)

1. Product Details (Name and other details, attach product label/ product sample if available)

Brand Name:	Batch No:
Generic Name:	NAFDAC No:
Name and Address of Manufacturer:	Expiry Date:

2. Indications for Use (Diagnosis)

Dosage	Frequency	Route of Administration

3. Date Medication Started (dd-mmm-yyyy)	4. Date Medication Stopped (dd-mmm-yyyy)

5. Reaction Stopped or Reduced After Drug Withdrawal?
☐ Yes
☐ No
☐ Doesn't apply

6. Reaction Reappeared After Drug Reintroduction?
☐ Yes
☐ No
☐ Doesn't apply

D. *CONCOMITANT MEDICINES

(All medicines taken within the last 3 months, including herbal and self-medication)

Brand or Generic Name	Dosage	Route	Date Started	Date Stopped	Reason for Use

E. *RELEVANT TESTS / LABORATORY DATA WITH DATES

F. OTHER RELEVANT HISTORY

Including Preexisting Medical Conditions:
☐ Pregnancy
☐ Smoking
☐ Kidney Problems
☐ Alcohol use
☐ Liver problems

Allergies _____

Others (Specify) _____

G. *REPORTER

1. Name and Address

Last Name:	First Name:
Address:	
City:	State:
Country:	Date:
Phone No:	Email:

2. Health Professional?
☐ Yes ☐ No

3. Occupation:

* MANDATORY FIELDS

FORMS ARE AVAILABLE AT www.nafdac.gov.ng AND CAN BE SENT TO npcadr@nafdac.gov.ng

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Template (9): Template for Reporting Adverse Events Following Immunization

Adverse Events Following Immunization Form

FEDERAL REPUBLIC OF NIGERIA
FEDERAL MINISTRY OF HEALTH

Identification number /____ - _____ - _____ - ____ - _____/ to be assigned by the LGA DSNO
Country code – State code – LGA code — Year – Case number

REPORTING FORM

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)
This form should be filled by the health worker in charge of the patient and sent to the LGA DSNO
*Fill this form **for ALL (serious and non serious** AEFI)*

1. REPORTING **Date of report : ____/____/_____**

Date of reporting ___/___/___	Full Names of the person reporting	Designation of person reporting ☐Physician ☐Pharmacist ☐Nurse ☐Other (specify)	Telephone number/email	Signature of the person reporting

State :	LGA	Ward	Health Facility/Vaccination Center

2. PATIENT's IDENTIFICATION

First / Last name	Full Address (with landmarks)	Birth-date dd/mm/yyyy ___/___/___	Age _____years _____months	Sex (tick) ☐ M ☐ F

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). *Use additional sheet if needed:*

3. VACCINES ADMINISTERED

Name of Vaccines Received within last 30 days	*Date of vaccination*	*Time of vaccination*	*Dose (e.g. 1st, 2nd...)*	*Administration*		*Batch/ Lot number*
				Route	*Site*	
						Vaccine
						Diluent
						Vaccine
						Diluent
						Vaccine
						Diluent
						Vaccine
						Diluent

Intervention: ☐Routine immunization ☐SIA ☐Other prescription (specify)_____
Strategy: ☐Fixed ☐Outreach ☐Mobile

4. ADVERSE EVENTS

Describe the AEFI (signs and symptoms)	Date & Time AEFI started (DD/MM/YYYY): ☐☐ /☐☐ /☐☐☐☐ . ☐☐ Hr ☐☐Min Was the patient hospitalized? ☐Yes ☐No Date patient notified event to health facility (DD/MM/YYYY): ☐☐ /☐☐ /☐☐☐☐
Treatment(s) received	Was this a serious AEFI? (tick) ☐Yes ☐No - ☐Hospitalised - ☐Incapacitated - ☐Life Threatening - ☐Death
Outcome: ☐ Recovering ☐ Recovered Completely ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died Date of latest information on the outcome (DD/MM/YYYY): _____ /_____ /_____	

Toll free numbers 08031230415 / 0803120416 ⋆ Send free sms to 20543 (PRASCO)

DOCUMENTATION AT STATE LEVEL :

Date AEFI report received from the LGA

Quality score of the report: ☐ Q0 ☐Q1 ☐ Q2 ☐ Q3 ☐ Q4
If data is incomplete, state the areas of gap:

State actions taken :

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Template (10): Template for Reporting Medical Device Incidents

MEDICAL DEVICE INCIDENT USER REPORT FORM

I. Patient Information:			
Name/Initials:	Sex: ☐ Male ☐ Female	Weight:	Age:
II. Medical Device Information:			
Name Of Medical Device:		Type Of Medical Device:	
Manufacturing Date:		Expiry Date:	
Reference/Registration Number:		Code/Mode No:	
Catalogue No:	Lot/Batch No:	Serial No:	
Manufacturer Name: Address: Phone:		Supplier Name: Address: Phone:	
Quantity Defective (Number):		Current Location:	
Has the manufacturer/supplier been contacted? ☐ Yes ☐ No (Keep the device till the supplier requests it. Please Do not discard the device or related consumables & packing. Do not send medical devices to NPC/NAFDAC unless you have been specifically asked to do so)			
III. Incident Information:			
Incident Description/Nature of Device Defect (includes any action by patient, career or healthcare professional, or by the manufacturer or supplier):			
Action Taken:			
Type of injury: ☐ Death ☐ Serious ☐ Non-Serious ☐ None		Date of Incident:	
IV. Reporter Information (Will Be Kept Confidential)			
Reporter's Name:		Position/Occupation:	
Organisation:		Address:	
Phone/Mobile No:		Email:	
V. Other Comments:			

Headquarters:
National Pharmacovigilance Center
National Agency for Food and Drug Administration and Control

Address:
NAFDAC Corporate Headquarters
Plot 2032, Olusegun Obasanjo Way
Zone 7, Wuse, Abuja, Nigeria.

For Enquires: 0700-1-NAFDAC (0700-1-623322)
+234(0)-1-4609750

Email: pharmacovigilance@nafdac.gov.ng
Website: www.nafdac.gov.ng

North Central Zonal Pharmacovigilance Centre Office:
University of Ilorin Teaching Hospital, Ilorin Kwara State.
North West Zonal Pharmacovigilance Centre Office:
Ahmadu Bello University Teaching Hospital Zaria, Kaduna State.
North East Zonal Pharmacovigilance Centre Office:
University of Maiduguri Teaching Hospital, Borno State.
South-South Zonal Pharmacovigilance Centre Office:
University of Benin Teaching Hospital, Edo State.
South West Zonal Pharmacovigilance Centre Office:
Lagos University Teaching Hospital Lagos State.
South East Zonal Pharmacovigilance Centre Office:
Federal University Teaching Hospital Owerri, Imo State.