Z / MC / NPVU / F / 001 version 01

FORM No.: / A e-pdf

ADVERSE DRUG REACTION, MEDICATION ERROR AND PRODUCT QUALITY PROBLEM REPORTING FORM

(Identities of reporter and patient will remain strictly confidential)

NATIONAL PHARMACOVIGILANCE UNIT (NPVU)

Zambia Medicines Regulatory Authority
Plot No.2350/M, Off Kenneth Kaunda Int'l Airport Rd,
ZAF-KKIA Bypass Route between HITACHI & Delta Auto
P.O. Box 31890,
Lusaka, ZAMBIA

Telephone: +260 211 432 356 / 50
Mobile: +260 956 521 094
WhatsApp: +260 956 521 094
Email: npvu@zamra.co.zm
pharmacy@zamra.co.zm

1. PATIENT INFORMATION

Patient initials:..... File No.: ..... Age:..... Date of birth: .....

Sex: Male ☐ Female ☐ Age of Pregnancy:.....Weight (kg):..... Height (cm): .....

2. DETAILS OF ADVERSE DRUG REACTION OR PRODUCT QUALITY PROBLEM OR MEDICATION ERROR

I am reporting on: 1. an Adverse Drug Reaction ☐ 2. a Product Quality Problem ☐ 3. a Medication Error ☐

4. Other (specify).....

Description of Adverse Drug Reaction or Product Quality Problem or Medication error:

.....

.....

Date Reaction Started: .....

Outcome: Recovered ☐ Date:..... Recovering ☐ Not Yet recovered ☐ Unknown ☐

Seriousness of the adverse drug reaction: Death ☐ Life threatening ☐ Disability ☐ Birth defect ☐

Caused / prolonged hospitalization ☐ Other (specify).....

Additional information *(e.g. Relevant medical history, medicines taken in the last 28 days, allergies, previous exposure, baseline test results / lab data)*.....

.....

3. MEDICINES / VACCINES / MEDICAL DEVICES TAKEN / USED BY THE PATIENT: (✔) *Tick against the **suspected** Medicines / Vaccines / Medical Devices*

Indicate all medicines the Patient is taking

(✔)	Trade / Generic Name & Batch Number & Manufacturer	Dosage	Route of administration	Start date (dd/mm/yy)	Stop date (dd/mm/yy)	Reasons for use
☐						
☐						
☐						
☐						

4. DETAILS OF THE PRODUCT IF SUSPECTING PRODUCT QUALITY PROBLEM(S)

Trade / Brand Name	Batch Number	Dosage Form & Strength	Expiry Date (mm/yyyy)	Container size / type	No. of samples (if submitted)

Source / Supplier of the product:..... Manufacturer:.....

5. DETAILS OF THE REPORTER

Name: ..... Profession: ..... Signature: ..... Date (dd/mm/yyyy):.....

Institution/Facility:..... Phone: ..... Email:.....

ADVICE ABOUT VOLUNTARY REPORTING

Responsibility to report:
The onus is on all members of the public, in particular healthcare professionals to report **all suspected** Adverse Drug Reactions or Product Quality Problems to the National Pharmacovigilance Unit (NPVU) of the Zambia Medicines Regulatory Authority.

Report even if:
- You are not certain the product caused the event.
- You do not have all the details.

Report adverse reactions / events resulting from:
- Medications (drugs, vaccines, biologicals, blood and blood products).
- Defective components, devices or test kits.
- Traditional and herbal medicines (give local name and/or botanical name).
- Medication errors.
- Treatment failure or reduced efficacy.

Report product quality problems such as:
- Suspected contamination.
- Questionable stability (e.g. visual signs of possible microbial growths, cracking).
- Defective components, devices or test kits (e.g. not working properly or leaking).
- Poor packaging or labeling.
- Therapeutic failures.

If there is need for additional information please attach an extra page.

Where to send the report
This report may be sent to NPVU through your health facility, nearest ZAMRA office, by email or mailed to the address given below.

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Note:
It is your professional responsibility to report all suspected adverse drug reactions, medication errors and quality problems of medicines and allied substances. This report will contribute to the improvement of drug safety monitoring in Zambia.

Send the filled in form via:
1. **Email:** npvu@zamra.co.zm, or
2. **WhatsApp:** +260 956 521 094

or
Upload on ZAMRA's Safety Watch Website.

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PLEASE USE THE ADDRESS PROVIDED BELOW - JUST FOLD, TAPE AND MAIL

Postage will be paid by addressee

No postage stamp is required if posted within the Republic of Zambia

NATIONAL PHARMACOVIGILANCE UNIT (NPVU)
THE ZAMBIA MEDICINES REGULATORY AUTHORITY
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