CONFIDENTIAL

SUSPECTED SIDE EFFECTS REPORTING FORM

"Saving Lives Through Vigilant Reporting"

Food and Drug Administration PHILIPPINES

FIELDS ARE MANDATORY. Please fill all fields as completely as possible.
Attach additional documents if necessary. See information overleaf.

○ Initial report ○ Follow-up

Version 6.0

PATIENT INFORMATION

*Patient's Name or Initials:_____ *Sex: ○ Male ○ Female Weight (kg): _____ Height (cm): _____

*Age (at time of onset): _____ Date of Birth (dd/mm/yyyy): ____/____/_____

Medical record number: _____ Patient's address _____

SUSPECTED MEDICINES / VACCINES

*Medicine/Vaccine (Reg. No. or Brand, if any)	Batch/Lot No.	Dosage & frequency	Route	Date started dd/mm/yyyy	Date stopped dd/mm/yyyy	Reason for using
				___/___/_____	___/___/_____	
				___/___/_____	___/___/_____	
				___/___/_____	___/___/_____	

SIDE EFFECT(S) / ADVERSE REACTION(S)

*Date started (dd/mm/yyyy): ____/____/_____ time:_____

*Describe the side effects or reaction or problem:

Relevant medical history and concurrent condition:
(Pertinent information to understand the case such as disease, conditions such as pregnancy, allergies, surgical procedures, psychological trauma, etc.)

Results of tests and procedures:
(Tests and procedures performed to diagnose or confirm the reaction/event, including those test done to investigate or to exclude a non-drug cause/ Results of test/procedures may be attached)

Do you consider the reaction to be serious? ○ yes ○ no

If yes, reason

- ☐ death (date:_____)
- ☐ hospitalization/prolonged (date of admission:_____)
- ☐ congenital-anomaly
- ☐ life-threatening
- ☐ disabling
- ☐ other medically important condition

Was this a medication error? ○ yes ○ no

Action taken:
- ☐ medicine withdrawn
- ☐ dose reduced
- ☐ no change

Is treatment given? ○ yes ○ no
If yes, please specify: _____

Outcome of reaction
- ☐ recovered (date:_____) with sequelae?
  - ○ no
  - ○ yes, describe:_____
- ☐ not yet recovered
- ☐ fatal
- ☐ unknown

Did the reaction recur on readministration of suspected medicine(s)?
○ yes ○ no ○ not applicable

List all other medicines/vaccines taken at the same time (including diluent)

Medicine/Vaccine(DR-XY No. or Brand, if any)	Batch/Lot No.	Dosage & frequency	Route	Date started dd/mm/yyyy	Date stopped dd/mm/yyyy	Reason for using

☐ no other medicines used

REPORTER INFORMATION

***Name:** _____

Address:_____

***Contact/Mobile No.:** _____

Email:_____

Signature/ initials: _____

Date of report (dd/mm/yyyy): ____/____/_____

***Reporter qualification:**

- ☐ **physician**
- ☐ **pharmacist**
- ☐ **other health professional**
- ☐ **patient/consumer**
- ☐ **nurse**
- ☐ **dentist**

Thank you for your time completing this form!

CONFIDENTIALITY

Any information including attachment/s related to the identities of the reporter and patient will be kept confidential.

The report is for safety information purposes and will not be used against the practice of the reporting healthcare professional.

WHAT TO REPORT

Please report any of the following:

- All serious adverse reactions
- All adverse reactions related to newly introduced medicines and vaccines
- Medication errors, lack of efficacy, overdose, off-label use that resulted to serious adverse reactions
- Adverse reactions suspected to be related to a product defect

Report even if you are not sure that the drug caused the event!

For follow-up reports:
Any follow-up information that has already been reported may be sent to us in another form or through other reporting channels. Please indicate that it is a follow up report.

HOW TO REPORT

Suspected adverse reaction may be reported through any of the following:

- Mail or Direct submission to:

  FOOD AND DRUG ADMINISTRATION
  Center for Drug Regulation and Research
  Civic Drive, Filinvest City, Alabang, Muntinlupa City 1781

  or
  FDA Regional Field Office near you

- Email to pharmacovigilance@fda.gov.ph
- Online reporting:
  https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH
- Telephone: (02) 8809 5596

This form can be downloaded from:

https://www.fda.gov.ph/pharmacovigilance/

WHY DO WE NEED TO REPORT

Every time you report a side effect you are contributing to improve the safety of medicines and vaccines used by Filipinos.

Drugs and vaccines are registered to and evaluated by the FDA considering the quality of the products. However, no medicine is guaranteed 100% safe. Although they are carefully tested and evaluated, some side effects or adverse reactions may become evident only after the product is in use by the general population.

Your report may contribute to:

- the identification of previously unrecorded or unrecognized rare or serious side effect;
- changes in product safety information or labelling, or other regulatory actions such as product recall or removal from the market;
- international data regarding benefit, risk or effectiveness assessment of medicines and vaccines;

Regulatory actions are imposed by the FDA to secure the safety of the public. It also provide consumers and healthcare professionals guidance on the rational use of medicines and vaccines.