Instructions for Completing
Suspected Adverse Event Reporting Form

A. PATIENT AND HOSPITAL INFORMATION

- **Name of health facility:** Enter the name of the health facility (if applicable) where the event was detected

- **Patient name:** Enter the patient's first and last name (surname)

- **Registration number:** Enter the patient's hospital registration number as it appears on hospital records

- **Age:** Enter the patient's age when the event occurred or date of birth (if known); if age and date of birth are unknown, enter approximate age

- **Patient address:** Enter the address where the patient can be reached

- **Contact number:** Enter the phone number where the patient can be reached

- **Weight:** Enter the patient's weight in kilograms; make a best estimate if unknown

- **Height:** Enter the patient's height in centimeters; make a best estimate if unknown

- **Gender:** Select the patient's gender

- **Pregnant:** Indicate if the patient was pregnant when the event occurred

B. SUSPECTED ADVERSE EVENT INFORMATION

- **Type of event:** Indicate whether the event was due to a suspected adverse drug reaction (ADR), product quality problem, or medication error

  o An **ADR** is any reaction that is fatal, life-threatening, or permanently or significantly disabling; requires or prolongs hospitalization; or relates to misuse or dependence (i.e., allergic reactions, effects from withdrawal, interactions with other medications, etc.).

  o A **product quality problem** relates to any product that is defective, deteriorated, or adulterated because of poor manufacturing practices, inadequate distribution and storage, poor labeling, or tampering. Counterfeit products would fall under this category.

  o A **medication error** is "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer." This can include prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

- **Suspected product:** Enter information about the suspected product including:

  o **Brand name:** Write the trade/brand/proprietary name

  o **Generic name:** Write the generic name

  o **Indication:** Write the reason the product was prescribed

- o **Start Date**: Indicate the first date the patient used the product

- o **End Date**: Indicate the last date the patient used the product

- o **Dose:** Indicate the dose (strength and unit)

- o **Dosage Form**: Indicate the dosage form (tablet, capsule, injection, etc.)

- o **Frequency:** Indicate how often the product was given/taken

- o **Batch/Lot number:** Write the batch/lot number (if available)

- o **Manufacturer:** Write the name of the manufacturer (if available)

- **Describe event including relevant tests and laboratory results:** Describe what happened when/after the patient took the medication, including any relevant tests and laboratory data.

  If available, list any baseline laboratory data prior to the administration or use of the medical product, all laboratory data used in diagnosing the event, any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event, pre and post-event medication levels and dates, and a synopsis of any relevant autopsy, pathology, engineering, or lab reports.

  - o **ADR:** Describe the event in detail, including a description of what happened and a summary of all relevant clinical information (medical status prior to event, signs and/or symptoms, differential diagnosis for event, clinical course, treatment, outcome, etc.)

  - o **Product quality problem:** Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medicine or health product can be understood. Examples of product problems can include discoloration or color change, separation of components, powdering/crumbling, caking, molding, change in smell, poor packaging, poor labeling and mislabeling, suspected contamination, questionable stability, defective components, and expired shelf life.

  - o **Medication error:** Include a description of the error, type of staff involved, work environment in which the error occurred, indicate causes or contributing factors to the error, location of the error, names of the products involved, manufacturer, dosage form, strength, concentration, and type and size of container.

- **Date event started:** Provide the actual or best estimate of the date of first onset of signs and symptoms of the adverse event.

- **Date the event was reported:** Write the date the patient reported the event or the health care worker detected the event

- **Date the event stopped:** Indicate when the event (signs and symptoms) stopped

- **Was the adverse event treated?** Indicate whether the adverse event was treated (yes/no); if yes, specify how

- **Action taken after the reaction:** Indicate any action that was taken after reaction

  o **Dose stopped:** The medication was stopped or discontinued
  o **Dose reduced:** The medication was given at a lower dose
  o **No action taken:** No action was taken

- **Did reaction subside after stopping/reducing the dose of the suspected product?** Check yes, no, or not applicable

- **Did reaction appear after reintroducing the suspected product?** Check yes, no, or not applicable

- **Seriousness of the adverse event:** Indicate the severity of the adverse event based on the following criteria:

  o **Not serious:** Little or no harm occurred to the patient as a result of the event

  o **Hospitalization or prolongation of hospitalization:** A patient is admitted to the hospital for one or more days or remains in the hospital for one or more additional days due to the adverse event; includes emergency visits and same day discharges

  o **Disability or permanent damage:** Substantial disruption of a person's ability to conduct normal life functions such as significant, persistent, or permanent change, impairment, damage, or disruption in the patient's body function/structure, physical activities and/or quality of life

  o **Congenital anomaly/birth defect:** Exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child

  o **Life threatening:** The patient was at substantial risk of dying at the time of the adverse event or use or continued use of the device or other medical product might have resulted in the death of the patient

  o **Other serious:** The event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes

  o **Death:** The adverse event resulted in death of the patient

- **Outcomes attributed to the adverse event**: Indicate the outcome attributed to the event

  o **Recovered:** Patient no longer has any signs and symptoms associated with the event

  o **Recovered/resolved with sequela:** Patient's initial signs and symptoms have abated, but further consequential complications have arisen

  o **Not recovered:** Patient's signs and symptoms have not abated; the patient's condition remains unchanged or has worsened

- o **Unknown:** Patient's event or outcome has not been stated by reporter

- o **Fatal:** Patient's event led to or contributed to death; enter the date the patient died

- **Other relevant history:** Please provide any other information that can help in the evaluation of the reported adverse event such as pertinent medical history (diabetes, hypertension, liver/kidney problems, etc.), race, allergies, smoking and alcohol use, etc.

C. OTHER CONCOMITANT PRODUCT INFORMATION

In this section, please enter information about any other concomitant products that the patient is taking including:

- **Brand name:** Enter the trade/brand/proprietary name

- **Generic name:** Enter the generic name

- **Indication:** Write the reason the medication was prescribed

- **Dosage form:** Indicate the dosage form (tablet, capsule, injection, etc.)

- **Route:** Describe how the product was used by the patient or given to the patient (by mouth, intravenous, intramuscular, etc.)

- **Dose:** Write the dose of the medication

- **Frequency:** Write how often the medication was administered/taken

- **Date started:** Write the date the medication was started

- **Date stopped:** Write the date the medication was stopped (if applicable)

D. REPORTER INFORMATION

- **Name:** Write the name of the person filling out the report

- **Designation:** Write the designation or title of the person filling out the report

- **Address:** Write the address of the institution with which the reporter is affiliated

- **Email address:** Write the email address of the reporter or hospital

- **Mobile phone:** Write the phone number of the reporter

- **Land phone:** Write the phone number of the hospital

- **Signature:** The reporter should sign the document once all applicable sections have been completed

- **Date of submission:** Write the date the form is submitted

These instructions are based on the US Food and Drug Administration's MedWatch form 3500 (Form FDA 3500) from the Safety Information and Adverse Event Reporting Program.