Concise guidelines on how to complete the safety yellow form

*Note: Sections highlighted in **BOLD** are mandatory fields in the form*

A. PATIENT INFORMATION:

1. **Patient initials or Hospital Reg. No.**: Enter only patient's initials. Hospital Registration number can also be used.
2. **Date of birth/ Age:** Indicate date of birth *or* age.
3. **Gender:** Tick male, female or unknown (unk).
4. **Weight:** Indicate weight in kilograms.
5. **Pregnancy:** tick Yes or No in the pregnancy status. If yes, please provide gestational period
6. **Known allergies:** Please provide patient's known allergies

B. ADVERSE EVENT INFORMATION:

1. **Type of report:**
   a. Tick "initial" box for first time reporting or Tick "follow up" box if reporting additional information of a case that was previously reported case.
   b. In case of it's a follow up, indicate the Adverse Medicine Reaction number (AMR ID) that TIPC sent to you along with the acknowledgement letter of the initial report.
2. **Description of Adverse Events.** Indicate the provisional or final diagnosis of the adverse event. Use different rows for each adverse event.
   a. **Date event started**: Record the onset date of the adverse event. Provide at least month and year.
      i. The date is important for the evaluation of the time relationship at the start date of the suspected medicine.
   b. **Date event stop:** Record the date when the patient recovered from the adverse event. Initial reports can be sent without this information.
   c. **Action taken**: Indicate the decision taken. Whether the medicine was withdrawn, substituted or the dose was reduced. If possible provide information if medical treatment was given. It will help to understand the patient outcome.
3. **Seriousness.** Indicate the seriousness criteria that the adverse event met: Hospitalization, Disability or permanent damage, congenital anomaly/birth defect, Life-threatening, other serious medical event. Please take note that if the event does not meet any of those criteria, then "Non serious adverse event" should be marked.
4. **Patient outcome**: Indicate the patient status at the time of reporting. Recovered, Recovered with sequel, Recovering, Not recovered or Unknown. Please note that this outcome is for the adverse medicine reaction not for the condition being treated.
   2. If the patient died indicate the date of death (at least month and year), and tick the option that better associates the cause of death and the adverse medicine reaction.

C. Relevant Laboratory test: Record all the laboratory tests that are relevant to the adverse event, especially for those adverse events that are linked to a lab abnormality.

   a. **Test date:** Indicate the date that the test was performed. Date is important to evaluate the time relationship with the start date of the treatment.
   b. **Result:** Record result with the appropriate measurement units.

D. Relevant Medical History: Record pre-existing medical conditions that may help to understand the general condition of the patient including: diabetes, liver, kidney, respiratory, cardiovascular problems, alcohol use etc.

E. INFORMATION ON MEDICINES

1. **List medicines used in the last 3 months.**
   ii. Provide brand name (or generic name if brand name not available) of the medicine as has been written in the prescription.
   iii. **Tick the SUSPECTED PRODUCT**. It is possible to tick more than one medicine, but at least one should be marked. **We will not be able to assess a report if there is no suspected product indicated.**
   iv. Enter fixed dose combinations (FDC) as one medicine.
   v. For vaccines, please complete the Adverse Event Following Immunization (AEFI) Report Form
2. **Dose, Frequency and route of administration**: Record the dose, frequency and route of administration of each medicine. This is important information as some adverse medicine reactions are dose related. (E.g. TDF/FTC/EFV: 300/200/600 mg/ od/oral)
3. **Start/stop date**. Record the treatment start date and the stop date if applicable. These dates are important to evaluate the time relationship between the Adverse Medicine Reaction and the treatment. Indicate "ongoing" when the medicine has not been stopped.
4. **Reason for use:** Record the medical condition that the medicine is given for (not the adverse reaction).

F. REPORTER INFORMATION:

1. **Name, profession, Region, Health Facility/ Practice Name:** Record reporter's details. Important to observe how each region is performing.**Telephone/fax/email.** Indicate your contact details. It will help us to keep you informed in medicine safety issues and to acknowledge receipt.
2. **Date:** Record date of reporting.