ADVICE ABOUT REPORTING ADVERSE EVENTS

- Report adverse experiences with Medications, Devices, and Vaccines

- Report serious adverse reactions. A reaction is serious when the patient outcome is:

  - Death
  - Is life-threatening;
  - Hospitalization
  - Required intervention to prevent permanent impairment /damage
  - Congenital anomaly
  - Disability

- Who can report?

  Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

- Where to report:

  Please fill the online form and submit.

- What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at G7 by using CDSCO guidelines as per May 2011. The analyzed forms are forwarded to the sponsor through the ADR database. Finally the data is analyzed and forwarded to the DCGI.

- The reports are periodically reviewed by the G7. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

INSTRUCTIONS TO FILL THE ADVERSE EVENT FORM

Complete all sections that apply. If information is unknown, not available or does not apply, the section should be left blank.

Section A

1. Enter patient's initials or some other type of identifier to make it convenient to search in case of follow up. Patients name or any other type of social identity should not be disclosed
2. Provide patient's age at the time of event onset with the date of birth. Most precise information available should be given.
3. Enter the patient's gender.
4. Indicate whether the weight in kilograms (kgs). Best estimate of exact weight should be made if weight is unknown

Section B

5. Enter the actual date when the reaction was first started in dd/mm/yy format. If day is unknown, month and year are accepted. If day and month are unknown, year is acceptable.
6. Enter the date for recovery of the event in dd/mm/yy format. If day is unknown, month and year are accepted. If day and month are unknown, year is acceptable.
7. Description of the event to be made in reporters own word, describing what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). Synopses of office note, discharge summary can also be included.

Section C

8. Trade name of the product as marketed should be used. If unknown or if no trade name generic name should be used with manufacturer or labeler's name. Batch No, Expiry date of the product, Dose , Route of administration with frequency date administration was started (or best estimate) and the date stopped (or best estimate). If dates are known, an estimated duration is acceptable (e.g., 2 years) or, if therapy was less than one day, then duration is appropriate (e.g., 1 dose or 1 hour for an IV).
9. Reaction Abated after drug Stopped or Dose Reduced: Check the appropriate box.
10. Reaction Reappeared after Reintroduction: Check the appropriate box.
11. List and provide therapy dates for any other medical products that a patient was using at the time of the event. DO NOT include products used to treat the reaction

12. Test results and laboratory data should be entered. Relevant negative test and laboratory findings can also be included. Any baseline lab data prior to use of the medical product, lab data used in diagnosing the event and for devices lab data /

engineering analyses can also be included. Lab reports, pathology reports, autopsy reports can be submitted as attachments without disclosing the patients identity.

13. Other relevant histories including pre-existing medical conditions if available, provide information on
    Allergies
    Race
    Pregnancy
    Smoking alcohol use
    Hepatic/renal dysfunction

14. Report serious adverse reactions. A reaction is serious when the patient outcome is:
    i. Death
    ii. Is life-threatening;
    iii. Hospitalization
    iv. Required intervention to prevent permanent impairment /damage
    v. Congenital anomaly
    vi. Disability

    i. Death:
    Check if death was an outcome of the adverse event, or if the cause of the death is unknown.
    DO NOT check if:
    • If there is no suspected association between the death and the use of the product when the patient died
    • A fetus is aborted because of a congenital anomaly, or is miscarried

    ii. Life-threatening: Check if suspected that:
    • If the death of the patient is due to use and continuous use of device
    • The patient was at substantial risk of dying at the time of the adverse event,

    iii. Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
    DO NOT check if:
    • A patient in the hospital received a medical product and subsequently developed another- wise non serious adverse event, UNLESS the adverse event prolonged the hospital stay
    DO check if:
    • A patient is admitted to the hospital for one or more days, even if released on the same day.

    iv. Disability: An impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual in executing a task or action

    v. Congenital Anomaly: newborn baby is found to have a congenital anomaly/birth defect that the initial reporter considers possibly associated with a product administered to the mother during pregnancy.

vi. Required Intervention to Prevent Permanent Impairment/Damage (Devices): if either situation may be due to the use of a medical device and medical or surgical intervention was necessary to:

- Preclude permanent impairment of a body function, or
- Prevent permanent damage to a body structure.

vii. Other Medically significant events.

15. Outcomes attributed to adverse event should be checked accordingly

Section D

16. Please provide Name, professional address with pin code, contact number and email id of the initial reporter who reported the event. The area in which the reporter is specialized should also be mentioned with the person's signature

17. Indicate the initial reporter's occupation

18. Date of the report to be mentioned in dd/mm/yy format