Instruction for filling CIOMS

Section I

1. Enter patient's initials or some other type of identifier to make it convenient to search. Patients name or any other type of social identity should not be disclosed.

1a. Country where the patient resides should be mentioned.

2. Provide patients date of birth. Most precise information available should be given.

2a. Provide patient's age at the time of event onset. Most precise information available should be given.

3. Enter the patient's gender.

4-6. 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.

7+13. 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. 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.

8-12. Report serious adverse reactions. A reaction is serious when the patient outcome is:

- Patient Died
- Involved or prolonged inpatient Hospitalization
- Involved persistence or significant disability or incapacity
- Is life-threatening
- Congenital anomaly
- Others

- **Patient died:**

  Check if death was an outcome of the adverse event, or if the cause of the death is unknown. Include the date of death, if known.

  DO NOT check if:

  • The patient died while using a medical product, but there was no suspected association between the death and the use of the product

- A fetus is aborted because of a congenital anomaly, or is miscarried

- **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.

- **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

- **Life-threatening:**

  - Check if suspected that:

- The patient was at substantial risk of dying at the time of the adverse event, or
- Use or continued use of the device might have resulted in the death of the patient

- **Congenital Anomaly:**

  If 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.

- **Other Medically significant events.**

Section II

14. Trade name of the product as marketed should be used. If unknown or if no trade name generic name should be used.

15. Describe how the product was used by the patient in terms of dose (e.g., 500 mg QID orally or 10 mg every other day IV).

16. Describe the route of administration of the product.

17. The disease condition for which the drug is being used.

18. Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If dates are known, an estimated duration is acceptable.

19. The overall duration of the therapy given to be provided.

20. Did the reaction abate after drug Stopped: Check the appropriate box.

21. Did the reaction reappear after Reintroduction: Check the appropriate box.

Section III

22. 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.

23. Other relevant histories including pre-existing medical conditions if available provide information on Allergies, Pregnancy with last menstrual period.

Section IV

24a. Provide Name and address of manufacturer with pin code, contact number

24b. Provide MFR control no.

24c.Date received by the manufacturer: Provide the date when the adverse event was received by manufacturer

24d.Report source: Mention whether the report was received by any study or by literature search or any health professional reported the event or was it through any regulatory authority.

25a. Report type: Mention whether the report is initial report or follow up.

26-26a.Provide Name, professional address with pin code, contact number and email id of the initial reporter who reported the event.