

A. Patient Information

1. *Patient initials: A reporter should only mention the initials of a patient instead of the full name. For e.g.: **Madhu Gupta** should be written as **MG**.*
2. *Age at time of event or date of birth: A reporter must report either the date of birth or age of the patient at the time the event or reaction occurred.*
3. *Sex: A reporter must mention the gender of the patient.*
4. *Weight: The weight of the patient should be in kilograms.*

B. Suspected Adverse Reaction

5. *Describe reaction: A reporter must briefly describe the event in terms of nature, localization etc. For example patient developed rash over upper and lower limbs. The reporter must report the date on which the reaction was first observed. If the reaction recovered, the date on which the reaction recovered should be reported.*

C. Suspected Medications

6. *The details of suspected Alkem's medication(s) such as the drug name (brand or generic name), batch no/lot no, expiry date, dose used, route used, frequency, dates of therapy started and stopped, and indication of use must be provided by the reporter.*

D. Reporter

7. *Name, address and Telephone number: A reporter must mention his/her name and address on the form and provide telephone number so that we can call back to get additional information about the event. The identity of the reporter will be maintained confidential*