‑

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Patient Details\*** | | | |
| Patient Initials \_\_\_\_\_\_\_\_\_\_\_\_ (write PKM for Pankaj Kumar Mishra) | | Country |  |
| Age / Date of Birth: \_\_\_\_\_\_\_\_\_\_\_ | Weight (in kg): \_\_\_\_\_\_\_\_ | Pregnant | □ Yes □ No □ Unknown |
| Gender: □ Male □ Female □ Other | | Date of LMP  (Last Menstrual Period) | In case of Pregnant, mention date of LMP DD/MM/YYYY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **(B) Suspected Medication(s) \*** | | | | | | | | | | |
| **S. No.** | **Product Name** | | **Manufacturer name** | **Batch number/ Expiry Date** | **Dose, Route & Frequency (OD/BD etc.)** | | **Therapy Start date**  DD/MM/YYYY | **Therapy Stop date**  DD/MM/YYYY | **Indication** | **# Action Taken** |
| **Brand Name** | **Generic Name with strength** |
| 1. |  |  |  |  |  | |  |  |  |  |
| 2. |  |  |  |  |  | |  |  |  |  |
| 3. |  |  |  |  |  | |  |  |  |  |
| # Select appropriate action taken:  Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable | | | | | | | | | | |
| Did event abated after drug withdrawn/ dose reduced?  □ Yes / □ No / □ Unknown / □ Not applicable | | | | | | Did event reappeared after reintroduction?  □ Yes / □ No / □ Unknown / □ Not applicable | | | | |
| Concomitant medications (Any other medications consumed along with our company drugs): | | | | | | | | | | |
| Drug Name | | Dose & Frequency | | Route | | | Therapy dates | | Reason for use | |
| From | To |
|  | |  | |  | | |  |  |  | |
|  | |  | |  | | |  |  |  | |
|  | |  | |  | | |  |  |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **(C) Adverse Event Details \*** | | | | |
| **Adverse event** | **Date of event Onset** | | **Date of event stopped** | **## Outcome** |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
| **##** Select outcome of adverse event: *Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal* | | | | |
| Is the adverse event serious? □ Yes / □ No  If yes, please indicate why it is serious? (Check all that apply)  □ Death □ Life threatening □ Hospitalization-Initial /Prolonged □ Congenital anomaly/birth defect □ Disability □ Other important medical event | | | | |
| If hospitalized provide:  Date of admission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of discharge \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | If Death, provide:  Date of death DD/MM/YYYY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Cause of death \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Description of adverse events: (including sign and symptoms with specific diagnosis, treatment): | | | | |
| Relevant Lab test Details (with dates, results and normal range) : | | | | |
| Other relevant history including pre-existing medical conditions: (e.g. allergies, smoking, alcohol use, liver/kidney problems etc.) | | | | |
| **Relationship of the adverse event with drug**: □ Related □ Not Related □ Unknown | | | | |

|  |  |
| --- | --- |
| **(D) Reporter details (Health Care Professional)\*** | |
| Name: | Qualification: |
| Address: | Occupation: |
| Email: | Phone No. |
| Date of this report : | Signature: |

**\* *Mandatory Fields for Adverse Event Reporting Form.***

**ADVICE ABOUT REPORTING**

|  |  |
| --- | --- |
| **Who can report?**  All healthcare professionals (Clinicians,  Dentists, Pharmacists, Nurse etc.) can report adverse event. | **Where to report?**  **Please Send the complete filled form to Email:**  Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **What to report?**  All adverse event should be reported.  Report all (serious / non-serious adverse event) occurred due to medicines. |
| **Confidentiality:** **The patient’s identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of this report does not have any legal implication on the reporter.** | |