|  |  |  |  |
| --- | --- | --- | --- |
| **Initial case** | **Follow up case** | | FOR HOSPITAL/PHARMACY/CLINICS USE ONLY |
| **A. PATIENT INFORMATION** | | | Reg. No./IPD No./OPD No./WARD No. : |
| 1. Patient Initials: | 2. Age or date of birth: | | Report No. : |
| 3. Gender: M  F  Other | 4. Weight (in Kg.) | | Worldwide Unique No. : |
| **B. SUSPECTED ADVERSE REACTION** | | | 12. Relevant investigations with dates: |
| 5. Event / Reaction start date (dd/mm/yyyy) | |  |
| 6. Event / Reaction stop date (dd/mm/yyyy) | |  |
| 7. Describe Event/Reaction management with details , if any | | | 13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.) |
| 14. Seriousness of the reaction : No**□** if Yes **□** (please tick anyone) Death (dd/mm/yyyy) Congenital-anomaly  Life threatening Disability  Hospitalization-Initial/Prolonged Other Medically important |
| 15. Outcome:  Recovered Recovering Not Recovered  Fatal Recovered with sequelae Unknown |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **C. SUSPECTED MEDICATION(S)** | | | | | | | | | | | |
| S. No. | Name (Brand/ Generic) | Manufactu rer (if known) | Batch No. / Lot No. | Expiry Date (if known) | Dose Route Frequency | Dose  Route  Frequency | Dose Route Frequency | Therapy Dates | | Indication Causality Date Assessment | Indication Causality Date Assessment |
| Date Started | Date Stopped |
| i |  |  |  |  |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 9. Action taken after reaction (please tick) | | | | | | |
| S. No. as per C | Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown |
| i |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 10. Reaction reappeared after reintroduction of suspected medication (please tick) | | | |
| Yes | No | Effect unknown | Dose (if reintroduced) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction) | | | | | | | |
| S. No. | Name (Brand / Generic) | Dose | Route | Frequency (OD, BD, etc.) | Therapy Dates | | Indication |
| Date Started | Date Stopped |
| i |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |

|  |
| --- |
| 12. Relevant investigations with dates: |
| 13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.) |
| 14. Seriousness of the reaction : No **□** if Yes **□** (please tick anyone)  Death (dd/mm/yyyy) Congenital-anomaly Life threatening  Disability Hospitalization-Initial/Prolonged Other Medically important |
| 15. Outcome:  Recovered Recovering Not Recovered  Fatal Recovered with sequelae Unknown |

|  |
| --- |
| **D. REPORTING DOCTOR/ PHARMACIST/ NURSE/ DENTIST/ OTHER** |
| **Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Address & Contact Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Electronic/ Paper Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Reporting: \_\_\_\_/\_\_\_\_\_/\_\_\_**  **\_\_\_** |