|  |  |
| --- | --- |
| **\***A. PATIENT INFORMATION | **ADR Report No. :** |
| **1. Patient Initials** | **2. Age at the time of Event or Date of Birth** | 3. M □ F □ Other □ | **Case ID/Worldwide Unique No. :** |
| 4. Weight KgsHeight cms | **Report Type: Initial □ Follow up □** |
| **\***B. SUSPECTED ADVERSE REACTION | 12. Relevant tests/ laboratory data with dates |
| **5. Event/Reaction start date (DD/MM/YYYY)** |
| **6. Event/Reaction stop date (DD/MM/YYYY)** |
| **7. Describe Event/Reaction with treatment details, if any** |
| 13. Relevant medical/medication history |
| 1. Seriousness of the reaction: No □ Yes □

(if yes, please tick anyone)* + Death (dd/mm/yyyy) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	+ Life threatening
	+ Hospitalization (Initial/Prolonged)
	+ Congenital-anomaly
	+ Disability
	+ Other Medically important
 |
| 15. Outcome* Recovered □ Recovering □ Not recovered
* Fatal □ Recovered with sequelae □ Unknown
 |
| **\*C. SUSPECTED MEDICATION(S)** |
| S.No 8 | Name (Brand/Generic) | Manufacturer (if known) | Batch No./ Lot No. | Exp. Date (if known) | Dose used | Route used |  Frequenc y (OD,BD, etc.) | Therapy dates | Indication | Causality Assessment |
| Date started | Date stopped |
| i |  |  |  |  |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |  |  |  |  |  |
| S.No 9 | Action taken (please tick) | 10. Reaction reappeared after reintroduction(please tick) |
| Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | Yes | No |  Effect unknown | Dose (if reintroduced) |
| i |  |  |  |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| iii |  |  |  |  |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |  |  |  |  |
| 11. Concomitant medication(s) |
| S.No | Name (Brand/Generic) | Doseused | Route used | Frequency (OD,BD, etc.) | Therapy dates |  Indication |
| Date started | Date stopped |
| i |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |
| Additional Information: | **\*D. REPORTER DETAILS** |
| 16. Name and Professional Address:Pin:\_ E-mail Tel.No.(with STD code) Occupation:\_ Signature:\_  |
| 17. Date of this report (DD/MM/YYYY): |
| **Helpline Call/Message Received by:**(Name and Sign of Receiver) |

Note: Please fill mandatory fields (\*)

|  |  |
| --- | --- |
| **For ADRs Reporting to Shilpa**  | **For ADRs Reporting to PvPI** |
| **Telephone:** Please call us on the numbers below.

|  |
| --- |
| Telephone and WhatsApp : +91 9866307771  |

**Email:** Mail Us: Pharmacovigilance@shilpamedicare.com  | **Call on PvPI Helpline/ 1800 180 3024 (Toll Free)****(9:00 AM to 6:00 PM)****Monday-Friday/ All Working days).****E-mail: pvpi.ipc@gov.in****ADR Mobile App: “ADR PvPI”** |