|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A.Source of AE/ Special Situation** | | | | | | | | | | | | |
| □ Written complaints □ telephonic □ voice message □ oral □ email messages  □ others (specify) | | | | | | | | | | | | |
| **B. Report Type (select more than one if necessary** | | | | | | | | | | | | |
| □ Any spontaneous reports of ADR / AE.  □ Any suspected transmission via a medicinal product  □ ADR/AE related to technical complaints  □ ADR/AE related to medical information queries  □ ADR/AE from named patient use  □ ADR/AE from non-interventional studies  □ Pregnancy or lactation exposure  □ Medication abuse  □ Medication misuse | | | | | | □ Medication overdose  □ Medication errors  □ Off-label use  □ Occupational exposure  □ Drug interaction  □ Falsified Medicinal Product  □ Unexpected therapeutic  □ Lack of efficacy  □ If Other please specify. | | | | | | |
| **C. Patient information** | | | | | | | | | | | | |
| Patient Initials: | Sex:  □ M □ F | | | Date of Birth | Age /Age Group | | | | Weight | Height | | Nationality |
|  | If pregnant,  which month | | |  |  | | | |  |  | |  |
| Medical History/Known allergies | | | | | | | | | | | | |
| **D. Suspected Pharmaceutical Products /Device/Other category** | | | | | | | | | | | | |
| Trade Name, Dosage Form& Strength | | Batch No /Lot No. | | | Exp.Date | | | Route | | | Generic Name | |
|  | |  | | |  | | |  | | |  | |
| Manufacturer | | Dose per Day | | | Date Started | | | Date Stopped | | | Prescribed for | |
|  | |  | | |  | | |  | | |  | |
| **Concomitant Medications / Other drugs taken during the last 3 months** | | | | | | | | | | | | |
| Trade Name, Dosage Form& Strength | | | Date Started | | Date Stopped | | | | Prescribed for | | | |
|  | | |  | |  | | | |  | | | |
| **E. Suspected Adverse Reactions/Drug Problem** | | | | | | | | | | | | |
| Describe the Reaction/Problems(Please list the most significant adverse reactions first –  (If necessary use additional blank page) | | | | | | | | | | | | |
| Date of onset\_\_\_\_\_or Reaction appeared after \_\_\_\_\_\_ days of treatment  Date reaction stopped\_\_\_\_\_\_\_\_  Did a similar reaction occur in this patient earlier □ Yes □ No  Related to similar drugs□ Yes □ No  If Yes please specify  If treatment given please specify | | | | | | | **Outcome**  □ Recovered /resolved on **\_\_\_/\_\_\_\_\_/\_\_\_\_\_**  □ Recovering/resolving  □ Not Recovered/not resolved (further information has to be provided as soon as possible  □ Resolved with sequelea  □ Fatal  □ Unknown | | | | | |
| **Seriousness: Do you consider the reaction as serious?** □ Yes □ No If yes, please indicate why?  □ Death (due to the reaction) □ Life Threatening □ Persistent disability  □ Hospitalization \_\_\_ initial or prolonged  □ Congenital anomaly/birth defect □ Other medically important condition, please specify | | | | | | | | | | | | |
| **F. Reporter Information** | | | | | | | | | | | | |
| Name\_\_\_\_\_\_\_\_\_\_\_ Profession\_\_\_\_\_  Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of Report \_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_ | | | | | Has this case been already reported to national health authority or any other organization?  If yes, to whom? \_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| Thank you for sending back this Safety Form  Email : [infopv@ispoman.com](mailto:infopv@ispoman.com)  Phone : 00968 24822132 / 24822134  Fax : 00968 24871342 | | | | | | | | | | | | |