**AF/01-17/01.0**

**CIOMS FROM**

|  |  |
| --- | --- |
| **SUSPECT ADVERSE REACTION REPORT** |  |
|  |
|  |  |  |  |  |  |  |  |  |  |  |

**I. REACTION INFORMATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS(first. Last) | 1.a Country | 2. Date of Birth | 2.a AgeYear | 3. Sex | 4-6 Reaction Onset | 8-12 Check All APPROPRIATE TO ADVERSE REACTION🗆 PATIENT DIED🗆 INVOLVED OR PROLONGED INPATIENT HOSPITALISATION🗆 INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY🗆 LIFE THREATING |
| Day | Month | Year | Day | Month | Year |
| 7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) |

**ii. SUSPECT DRUG(S) INFORMATION**

|  |  |
| --- | --- |
| 14. SUSPECT DRUG(S) (Include generic name) | 20. DID REACTION ABATE AFTER STOPPING DRUG? 🗆YES 🗆 NO 🗆 NA |
| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION 🗆YES 🗆 NO 🗆 NA |
| 17. INDICATION(S) FOR USE |
| 18. THERAPY DATES (from/to) | 19. THERAPY DURATION |  |

**III.CONCOMITANT DRUG(S) AND HISTORY**

|  |
| --- |
| 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) |
| 23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergic, pregnancy with last month of period, etc.) |

**IV. MANUFACTURE INFORMATION**

|  |  |
| --- | --- |
| 24a. NAME AND ADDRESS OF MANUFACTURER |  |
| 24b. MFR CONTROL NO. |
| 24c. DATE REVIEVED BY MANUFACTURER | 24d. REPORT SOURCE🗆STUDY 🗆 LITERATURE 🗆 HEALTH PROFESSIONAL |
| DATE OF THIS REPORT | 25a. REPORT TYPE🗆 INITIAL 🗆 FOLLOW UP |