**AF/01-17/01.0**

**CIOMS FROM**

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| **SUSPECT ADVERSE REACTION REPORT** |  | | | | | | | | | | |
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**I. REACTION INFORMATION**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS  (first. Last) | 1.a Country | 2. Date of Birth | | | 2.a Age  Year | 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**

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| 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 |