**SUSPECT ADVERSE REACTION REPORT**

CIOMS FORM

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  PATIENT DIED  INVOLVED OR  PROLONGED  INPATIENT  HOSPITALISATION  INVOLVED  PERSISTENT OR  SIGNIFICANT  DISABILITY OR  INCAPACITY  LIFE THREATENING |
| (first, last) |  | Day | Month | Year | Years |  | Day | Month | Year |
| 7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) | | | | | | | | | |

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

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| --- | --- | --- |
| 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 REINTRO-DUCTION?  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. diagnoses, allergies, pregnancy with last menstrual period, etc.) |

**IV. MANUFACTURER INFORMATION**

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