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| <p><b>SUSPECT ADVERSE REACTION REPORT</b></p> |  |
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**I. REACTION INFORMATION**

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

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

|  |                                |   |
|--|--------------------------------|---|
| 14. SUSPECT DRUG(S) (include generic name) |                                | 20. DID REACTION ABATE AFTER STOPPING DRUG?<br><input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA     |
| 15. DAILY DOSE(S)                          | 16. ROUTE(S) OF ADMINISTRATION | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION?<br><input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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, allergics, pregnancy with last month of period, etc.) |

**IV. MANUFACTURER INFORMATION**

|                                       |  |
|---------------------------------------|--|
| 24a. NAME AND ADDRESS OF MANUFACTURER |  |
|                                       | 24b. MFR CONTROL NO.   |
| 24c. DATE RECEIVED BY MANUFACTURER    | 24d. REPORT SOURCE<br><input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE<br><input type="checkbox"/> HEALTH PROFESSIONAL |
| DATE OF THIS REPORT                   | 25a. REPORT TYPE<br><input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP   |