

SMC/SMD/GEN- 09/1.0

**ADVERSE REACTION REPORTING FORM**

**(Please complete all sections as much as possible)**

# (A) PATIENT DETAILS

Age/Date of Birth (dd/mm/yyyy): / / Wt (kg): ………………………………. Gender: M ( ) F ( ) If female, Pregnant Yes ( ) No ( ) Age of pregnancy……………………..

Name/Folder Number …………………………… Telephone No:………………… ……….

Hospital/Treatment Centre…………………………………………………………………………………

1. **DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN** (Attach a separate sheet and all relevant laboratory

 tests/data when necessary)

Date reaction started (dd/mm/yyyy): / / Date reaction stopped (dd/mm/yyyy): / /

1. **OUTCOME OF ADVERSE REACTION:**

Recovered ( ) Not yet recovered ( ) Unknown ( )

Did the adverse reaction result in any untoward medical condition? Yes ( ) No ( ) If yes, Specify………

**SERIOUSNESS**: Death ( ) Life threatening ( ) Disability ( ) (specify)…………… Hospitalization ( ) Others (specify)…………………….

1. **SUSPECTED PRODUCT(S)** (Attach sample or product label if available)

**Brand name**  **Generic name**  **Batch Number**  **Expiry date**  **Manufacturer**

**Reasons for use (Indication):**  **Dosage Regimen: No. of days Route of Administration:**

**given:**

Date started: (dd/mm/yyyy) / / Date stopped: (dd/mm/yyyy) / / *Did the adverse reaction subside when the drug was stopped (de-challenge)*? Yes ( ) No ( ) **Was the product prescribed? Yes No**  **Source of Drug:**

Was product re-used after detection of adverse reaction (re-challenge)? Yes ( ) No ( ) Did adverse reactionre-appear upon re-use? Yes ( ) No ( )

|  |
| --- |
| **(E)** **CONCOMITANT DRUGS: INCLUDING COMPLEMENTARY MEDICINES, CONSUMED AT THE SAME TIME AND/OR 3 MONTHS BEFORE**  |

(Attach a separate sheet when necessary)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Drug**   | **Daily dose**   | **Date started**   | **Date stopped/ Ongoing**   | **Reason(s) for use**   |
|   |   |   |   |   |
|   |   |   |   |   |
|   |   |   |   |   |

# ( F) REPORTER DETAILS

Name of Reporter: ……………………………………….…Profession……………………….. Institution’s

Address:………………………………………………………………………..……

Signature: …………………………Tel…………………E-mail…………………..…………….

Date (dd/mm/yyyy) : / /

 *\*****Confidentiality****: Identities of the reporter and the patient will remain strictly confidential\**