**Annexure 12**

Annexure 12

REPORT OF ADVERSE REACTIONS TO MEDICINES, VACCINES, DEVICES, TRADITIONAL REMEDIES & COSMETICS

(Identities of Reporter, Patient and Institution will remain confidential)

PATIENT DETAILS:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **BHT/Record no.** | **Name& address(optional)** | **Age** | **Ethnicity** | **Sex** | **M** |
| **F F** |
|  |  |  |  |  |  |

ALL MEDICINES IN USE:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Suspected Drug-generic & trade name( batch no if available) | Dose &  frequency |  | Route | Date  Begun | Date  Stopped | Reason for Use |
|  |  |  |  |  |  |  |
| Other Drugs in use: | | | | | | |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

DESCRIPTION OF ADVERSE REACTION:

System involved

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| RESP | CVS | GIT | CNS | GUT | SKIN | OTHER |
|  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |

Date of Onset:

Description of the event: Lab investigations if any:

Outcome: tick "√"or circle "o"

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Recovered | Continuing | Hospitalized | Severity | | | | Date of Death | Birth defect:  Specify: |
| Mild | Moderate | Severe | Fatal |

Result on discontinuation of suspect drug: √ Result on reintroduction of drug Alternative diagnosis

|  |  |  |  |
| --- | --- | --- | --- |
| Improved | Disappeared | Persisted | Not Known |
|  |

Reappeared: Yes/ No/ Not known

Risk factors present: √

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Renal  Dysfunction | Cardiac  Dysfunction | Hepatic  Dysfunction | Previous Allergies | Smoking | Alcohol | Drug addict | Other (name) |
|  |
| REPORT ON MEDICAL DEVICE/COSMETIC/QUALITY PROBLEM | | | | | | | |
| Name (Brand & Generic): | | | Device | Cosmetic | Drug | Date of expiry: | |
| Manufacturer (Name & Address): | | | | | | Model/Serial/Batch/Other Number: | |
| Description of the problem: | | | | | | | |

REPORTING DOCTOR/ PHARMACIST/ NURSE/ DENTIST/OTHER

Name & Designation:………………………………………………………………………..\

Address: …………………………………………………………………………………

………………………………………………………………...

Telephone Number: ………...………………… Hospital & Ward No: …….....…………….

Signature: ………...………………………… Date of Reporting: …../…../……