**PVF 01**

**PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION**

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| --- | --- | --- | --- | --- | --- |
| **Spontaneous Adverse Drug Reaction (ADR) Report Form** | | | | | |
| Identities of Reporter, Patient and Institute will remain confidential | | | | | |
| **MCAZ Reference Number** (MCAZ use only) | |  | | | |
| **Patient Details** | | | | | |
| **Clinic/Hospital Name:** |  | | **Clinic/Hospital Number** | |  |
| **Patient Initials:** |  | | **VCT/OI/TB Number** | |  |
| Date of Birth: |  | | Weight (Kg) | | **Sex:** |
| Age: |  | | Height (meters) | |
| **Adverse Reaction** | | | | | |
| Date of Onset: |  | | | | |
| Duration: | Less than one hour | Hours | Days | Weeks | Months |
| Description of ADR: |  | | | | |
| Serious: Yes  No | Reason for Seriousness | Death | | Life-threatening | |
| Hospitalization/prolonged | | Disabling | |
| Congenital-anomaly | | Other medically important condition | |
| **Current Medication** (including OTC and herbals) | | | | | |
| Generic/Brand Name | Batch No. | Dose and frequency | Date started | Date stopped | Tick Suspected medicine(s) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Relevant Past Drug Therapy** | | | | | |
| Generic/Brand name | Batch No. | Dose and frequency | Date started | Date stopped | Tick Suspected medicine(s) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Relevant Medical History |  |  |  |  |  |
| Laboratory tests results: |  |  |  |  |  |
| **Action taken:**   * Drug withdrawn * Dose increased * Unknown * Dose reduced * Dose not changed * Not applicable | | **Outcome of ADR:**   * Recovered/resolved * Recovering/resolving * Recovered/resolved with sequelae * Not recovered/not resolved * Fatal * Unknown | | | |
| **Reported by** | | | | | |
| Forename(s) & Surname: |  | | | | |
| Designation: |  | | | | |
| Email Address: |  | | | | |
| Phone Number |  | | | | |
| Name & Address of Institution |  | | | | |
| **Send to:** The Director-General, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, P O Box 10559, Harare  **Tel:** +263-4-708255 or 792165, **E-mail:** mcaz@mcaz.co.zw, **website:** [www.mcaz.co.zw](http://www.mcaz.co.zw), **online:** www.e-pv.mcaz.co.zw | | | | | |

**NB. This form may be completed for any ADR related to medicines or medical devices.**

**Please attach any other additional information, including an anonymized picture of the ADR (with patient’s consent)**