**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| **Action taken:*** Drug withdrawn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)**