Pharmaceutical Products: Suspect Adverse Reaction/Event Reporting Form

To be sent to Global Fund Quality Assurance Team at following Email address: healthproductqualityassurance@theglobalfund.org

This reporting form includes information regarding suspect adverse reaction, quality defect, deficiencies, or adverse events with health products circulated through the Global Fund (the “Health Information”). The Health Information may be circulated within the Global Fund organization and/or transferred to other international organizations, national regulatory authorities, health product manufacturers/suppliers, or procurement agencies.

#### Health Information Section

#### Patient Particulars

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient Initials (first, last) | Country | Age (Years) | Sex (m/f) | Weight (Kg) |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

#### Details of Adverse Drug Reaction (ADR)

|  |  |
| --- | --- |
| Reaction onset  |  Outcome |
| (Day/ Month/Year)Click or tap here to enter text. | [ ] Resolved with Sequelae[ ] Recovering | [ ] Fatal[ ] Not recovered | [ ] Recovered[ ] Unknown |
| DESCRIBE REACTION(S) (including relevant tests/lab data)Click or tap here to enter text. |
| Did reaction abate after stopping drug? □ yes □ no □ justifiyClick or tap here to enter text. |
| Did reaction reappear after reintroduction? □ yes □ no □ na |
|  |

#### Suspect Drug(s) Information

|  |
| --- |
| Suspected Drug(s) (Please specify brand name including generic name): Click or tap here to enter text. |
| Dosage: Click or tap here to enter text. | Route(s) of Administration: Click or tap here to enter text. | Frequency: Click or tap here to enter text. |
| Indication(s) for Use: Click or tap here to enter text. |
| Start Date of Therapy/ End Date of Therapy:Click or tap here to enter text. |

#### Concomitant Drug(s) and History

|  |
| --- |
| Concomitant drug(s) / Dose and Route / Indications and dates of administration (exclude those used to treat reaction)Click or tap here to enter text. |

#### Management of Adverse Reaction

|  |  |
| --- | --- |
| Did you report the defect to any of the following entities: the regulatory authority in charge, the manufacturer, its distributor, the importer? | [ ]  yes / [ ]  noIf yes, please specify to which entity:Click or tap here to enter text. |
| Name and address of any regulatory authority notified of the problem (if applicable) | Click or tap here to enter text. |

|  |
| --- |
| Do you consider this reaction to be serious? / Seriousness criteria Click or tap here to enter text. |
| [ ] Life threatening[ ] Involved persistent or significant disability or incapacity[ ] Congenital anomaly/birth defect[ ] Medical significant, please give details[ ] Involved or prolonged in-patient hospitalization |
| Treatment givenClick or tap here to enter text. |
| HospitalizationClick or tap here to enter text. |

|  |
| --- |
| Event OutcomeClick or tap here to enter text. |
| [ ] Resolved with Sequelae[ ] Recovering | [ ] Fatal[ ] Not recovered | [ ] Recovered[ ] Unknown |

#### Manufacturer Information

|  |
| --- |
| Name and address of manufacturerClick or tap here to enter text. |
| Batch control no.Click or tap here to enter text. |

#### Personal Information Section

**YOU MUST READ THE PRIVACY STATEMENT BEFORE COMPLETING THIS SECTION**

***PRIVACY STATEMENT***

***Available at following:*** [***https://www.theglobalfund.org/media/15326/corporate\_qa-reporting-forms\_privacy\_en.pdf***](https://www.theglobalfund.org/media/15326/corporate_qa-reporting-forms_privacy_en.pdf)

[ ]  I herewith acknowledge that I have read and understood the Privacy Statement applying to the personal information section

DateClick or tap here to enter text.

TitleClick or tap here to enter text.

SignatureClick or tap here to enter text.

#### Contact Details of the Reporting Organization

|  |  |
| --- | --- |
| Name of organization:Click or tap here to enter text. | Street Name and No.:Click or tap here to enter text. |
| City and postcode:Click or tap here to enter text. | Country:Click or tap here to enter text. |
| Telephone:Click or tap here to enter text. |
| Name of contact person:Click or tap here to enter text. | Email of contact person:Click or tap here to enter text. |

|  |
| --- |
| This part is reserved for Global Fund Staff |
| Date of reception of report:Click or tap here to enter text. |
| Report Number:Click or tap here to enter text. |
| Patient Identification Number:Click or tap here to enter text. |