Pharmaceutical Products: Quality Defect Reporting Form

To be sent to Global Fund Quality Assurance Team at following Email address:

[healthproductqualityassurance@theglobalfund.org](mailto: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.

#### Product Details / Extent of The Problem

|  |  |
| --- | --- |
| Information required | Information obtained |
| Name of product affected by the problem | …… |
| Authorisation number or other reference number | …… |
| Marketing Authorisation Holders or importers name and address (see package) | …… |
| Pharmaceutical form | …… |
| Active ingredient(s) (INN) | …… |
| Manufacturer’s name and address (final product) | …… |
| Lot number(s) concerned (manufacturing date(s) / strength / expiry date(s) / batch size(s) / type(s) of packs / number of packs) | If needed please attach separate list  …… |
| Distribution of the lots concerned (countries / clients delivered e.g. wholesale distributors, hospitals, pharmacies, doctors [lot number(s), number of pack(s), date of delivery]) | If needed please attach separate list  …… |
| Other products involved (name / authorisation number or reference number) | …… |

#### Nature of Defect(s)

|  |  |
| --- | --- |
| Information required | Information obtained |
| Where was the product defect noticed | Patient  Hospital  Pharmacy  Manufacturer  …… |
| Details of defect or problem | …… |
| Is the problem associated with any adverse event?  If so please specify | Yes No  …… |
| Is there any evidence or suspicion of a risk to public health (adverse effects or inefficacy)? | Yes No |
| Classification of defect (I, II or III), please justify | …… |

#### Action Taken and Proposed

|  |  |
| --- | --- |
| Information required | Information obtained |
| Did you report the defect to any of the following entities: the regulatory authority in charge, the manufacturer, it’s distributor the importer? | yes /  no  If Yes, please specify the date:Click or tap here to enter text.  If yes, please specify to which entity: |
| Name and address of any regulatory authority notified of the problem (if applicable) | …… |
| Action taken so far (if any) | …… |
| Batch or product recall proposed | Yes No  …… |
| Please indicate what happens to the pack(s) withdrawn | …… |
| Further action planned or proposed | …… |
| Other relevant information | …… |

Note: Documents providing additional information can be attached to this form; please list them hereunder: 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. |