ATTACHMENT 1: INCIDENT REPORT FORM

▪ INCIDENT REPORT FORM ▪

Date Completed:
Date Received by Americares:
Americares Case Number:

88 Hamilton Avenue, Stamford, CT 06902
(800) 486-4357 ▪ Fax (203) 327-5200 ▪
www.Americares.org

For Emergency or Adverse Event Reporting, call the Americares Adverse Event Hotline 203-658-9658 and fax and/or email the completed Americares Incident Report Form to the Americares Adverse Event Reporting Team at 203-327-5200, or adverseevents@americares.org

I. Organization Contact Information Section

Organization Name:			
Address	Street / PO Box:		
	City:	State/Province:	
	Postal Code:	Country:	
Phone:		**Fax:**	
Primary Contact Name:		**Title:**	
Email Address:			
Phone:	Home:	Work:	Mobile:
Alternate Contact Name:		**Title:**	
Email Address:			
Phone:	Home:	Work:	Mobile:

II. Product Incident Description Section

A. Please identify what type of incident occurred:

☐ Adverse event	☐ Product Quality Issue	☐ Product Use Error

B. Please describe the situation details below:

Location of incident:	
Date of incident:	**Number of people affected:**
Description of Person(s) Affected (Include age, male/female, weight, etc): * Do not include actual names *	
Person(s) Pre-Existing Medical Condition(s):	**Person(s) Concomitant Medical Treatment(s):**
Detailed description of what occurred:	
Event Abated: After Use Stopped? ☐ Yes ☐ No **After Dose Reduced?** ☐ Yes ☐ No ☐ N/A	
Supporting Lab Tests and Dates:	

C. Outcomes Attributed to Incident: (Select all that apply)

☐ Congenital Anomaly / Birth Defect	☐ Hospitalization (initial or prolonged)
☐ Death (date – mm/dd/yy): _____	☐ Life-threatening
☐ Disability or Permanent Damage	☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Device)	☐ Illness/Symptoms

D. Please complete the following information regarding the product:

Suspected Product Name:	
NDC Number (if available):	
Product Dosage:	**Dose:** **Frequency:** **Route:**
Indication:	
Product Lot #:	
Product Expiration Date:	

Do you still have additional stocks of this item?	☐ Yes ☐ No ☐ Unknown ☐ N/A
Do your sub-recipients have stocks of this item?	☐ Yes ☐ No ☐ Unknown ☐ N/A

***If yes, please quarantine stocks at all locations and do not distribute additional items until this situation has been assessed.**

E. If Medical Device event, please complete the following information regarding the product:

Suspected Product Brand Name/Common Device Name:		
Manufacturer Name:	**City:**	**State:**
Model# : **Lot# :** **Serial# :** **Catalogue# :** **Expiration Date:**		
Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other: (please explain)		
If implanted, provide date:		
Do you still have additional stocks of this item? ☐ Yes ☐ No ☐ Unknown ☐ N/A		
Do your sub-recipients have stocks of this item? ☐ Yes ☐ No ☐ Unknown ☐ N/A		

***If yes, please quarantine stocks at all locations and do not distribute additional items until this situation has been assessed.**

III. Other Incidents Section

Please identify the incident type and complete the information below, where applicable:

☐ **Customs Clearance Problem** (Select all that apply below)

☐ Paperwork delay

☐ Change in regulations

☐ Demurrage Fees accumulating - Fees incurred to date: $ _____ (USD)

☐ Fees will be paid ☐ Exemption being sought for fees ☐ Unable to pay fees

Please explain the above selection(s) and describe next steps to be taken:

☐ **Product Diversion**

Please describe the location where product diversion was discovered and steps being taken to address the issue:

☐ **Warehouse Theft**

Please describe the incident and items stolen:

☐ **Negative Media Report(s)**

☐ Print Media ☐ Television Report ☐ Internet Report

Please attach a copy of the article or describe the report:

☐ **Legal Action being taken against organization**

Please describe the situation and next steps:

☐ **Other (Explain Below):**

Please describe situation:

Name/Title of Person Completing Form **Date** **Signature**