

**Instructions:**

1. Use this form to report deficiencies or defects of medical products
2. Problems of this nature are usually found in a single batch of a product.
3. Do not report ADR using this form.
4. Use a separate form for different product defect complaints.
5. Return the completed form to Medical Product Division at [mpd@bfda.gov.bt](mailto:mpd@bfda.gov.bt)

1. Details of reporter (i.e patient, customer, and client):	
Name & Address	
Phone No & e-mail ID	
2. Product Details (Mandatory)	
Brand name:	
Generic name:	
Composition (with strength) or components:	
Batch no.	
Name & Address of the Manufacturer:	
Mfg. Date	
Expiry Date:	
3. Details of the Product Defect: (Mandatory)	
Was the defect encountered during the use of product	Please tick one: <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes: Was the product used/dispensed as per the manufacturer's instruction? .....
Description of the Defect/Problem:	

4. Details on Stock Balance and Storage: (Mandatory)	
Do you have Stock Balance of the same batch product?	Please tick one: <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> If Yes: mention the stock balance here.....
Where was the product stored?	Please tick one: <input type="checkbox"/> Store Room <input type="checkbox"/> Dispensary <input type="checkbox"/> Others If others, give details: .....
Storage Temperature (in degree Celsius)	(Please report the storage temperature as indicated on the thermometer at the time of reporting):..... Note: Use <b>Cold Chain Breakage Incident Complaint Form</b> in case, if the storage temperature is out of range (+2°C to +8°C) for vaccines.

Submitted by(Name):	Signature:	Date:
Occupation/Position:	Institution/Organization and Address:	Phone No & e-mail ID:

**FOR OFFICIAL USE ONLY:** Use MPD-WI-VL-08-01/ MPD-WI-VL-08-02/ MPD-WI-VL-08-03 to categorize the product defect and tick appropriate boxes:

- ☐ Critical   ☐ Major   ☐ Minor   ☐ Not sure  
☐ Convene Recall Committee Meeting   ☐ Send for testing

<b>Assessed by:</b>	<b>Verified by:</b>