

Note: vaccines are delicate biological substances that can become less effective or destroyed if they are not stored within +2 °C to +8 °C or frozen or exposed to heat or direct sunlight or fluorescent light. Therefore, in all instances where vaccines are exposed to temperature outside the recommended temperature, please report to the MPD, BFDA.

Instructions:

- i. *This Form is used to report incidence of cold chain breakage*
- ii. *Isolate the vaccines in an environment and clearly label “Quarantine/Do not use”*
- iii. *Do not discard any vaccines until advice has been sought from Ministry of Health (VPDP) or MPD*
- iv. *Take active steps to correct and prevent the problem recurring*
- v. *Return the completed form to MPD at mpd@bfda.gov.bt*

1. Vaccine Details	
Brand name:	
Generic name:	
Composition (with strength):	
Batch no.	
Name & Address of the Manufacturer:	
Expiry Date:	
2. Details of the incidence of cold chain breakage and description	
Types of incidences:	1. Fridge failure <input type="checkbox"/> 2. Power outage <input type="checkbox"/> 3. Transport issue <input type="checkbox"/> if others, specify.....
3. Details on Stock Balance and Storage:	
i. Date of breach	
ii. What was the temperature, when the breach was noticed (minimum and maximum)?	
iii. How long was the temperature outside +2° C to +8° C?	

iv. When was the accuracy of the thermometer last checked?	
v. Are the vaccines stored in their original packaging:	
vi. What kind of refrigerator used? UN prequalified with backup or domestic use?	
vii. Last maintenance date of refrigerator?	
viii. Does the refrigerator have fitted alarm?	
ix. What do you think could be the reason for cold chain breakage?	
x. Has the cause of CCB being corrected?	
xi. Has anybody being vaccinated with the potentially affected vaccines?	
4. Details on Stock Balance and Storage	
Actions undertaken by practice/clinic reporting incident:	
Do you have Stock Balance of the same batch product:	Please circle one: YES/NO If yes: How many?.....

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

FOR OFFICIAL USE ONLY:

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

Assessed by:	Verified by: