Reporter, patient & institution identities will remain confidential *Questions with an asterisk(*) sign are mandatory*			
□ First Report	□ Follow Up Report		

1) Patient Details *

Name (or initials)					
Gender		□ Male	□ Female	□ Pregnant □ Lactating	
Date of birth		Weight (kg)		Height (cm)	
Age at onset					

2) Risk Factors *

□ Renal disease	□ Hepatic disease	□ Cardiac disease
□ Smoker □ Occasional □ Frequent	□ Supplement/ Specify:	□ Other medical condition/ Specify:
□ Alcohol intake □ Occasional □ Frequent	□ Allergy/ Specify:	

3) Product(s) Details *

Medicine(s)

	Medicine Brand Name + Active Ingredient	Indication	Off Label Use	Batch Number	Expiry Date	Dose, Frequency, Dosage Form & Route of Administration	Started on			Stopped on		
Suspected Medicine(s)							Day	Month	Year	Day	Month	Year
							Day	Month	Year	Day	Month	Year
							Day	Month	Year	Day	Month	Year
Concomitant Medicine(s)							Day	Month	Year	Day	Month	Year
							Day	Month	Year	Day	Month	Year
							Day	Month	Year	Day	Month	Year

Vaccine(s)

Health Facility / Vaccination Center Name & Address	

Name of Vaccine	Expiry Date	Batch Number	Dose (1st, 2nd, etc.)	Date of Vaccination	Time of Vaccination	Route of Administration (IM, SC, Oral)	Site of Injection	For Diluent (if applicable)			
								Name of Diluent	Expiry Date	Batch Number	Date & Time of Reconstitution

4) Adverse Event *

Country of Occurrence	

In case of Medicine(s) Use

Suspected Adverse Event	**Onset Date**			**Recovery Date (if applicable)**		
	Day	**Month**	**Year**	**Day**	**Month**	**Year**

In case of Vaccine(s) Use

Suspected Adverse Event Following Immunization		**Onset Date**				**Recovery Date (if applicable)**			
		Time (Hr, Min)	**Day**	**Month**	**Year**	**Time** (Hr, Min)	**Day**	**Month**	**Year**
Local Reaction (Redness, Swelling)	□								
Fever≥ 38 □C	□								
Allergy	□								
Fatigue	□								
Headache	□								
Pain at the Injection Site	□								
FebrileSeizures Afebrile Seizures	□ □								
Abscess	□								
Sepsis	□								
Encephalopathy	□								
Toxic Shock Syndrome	□								
Thrombocytopenia	□								
Anaphylaxis	□								
Other/ Specify:									

Adverse Event Description / Case Narrative (Development, Symptoms, Management, etc.)

Relevant Laboratory and Diagnostic Tests Performed	**Date**			**Result**
	Day	**Month**	**Year**	

	Day	**Month**	**Year**	

5) Seriousness of Adverse Event *

Serious	□ Yes □ No	**If yes, please indicate why**		
		The Adverse Event led to:		
		□ Death	**Date of death**	
			Cause of death	
		□ Life Threatening Situation		
		□ Hospitalization		
		□ Prolongation of Hospitalization	**Specify additional duration**	
		□ Surgical Intervention		
		□ Congenital Anomaly		
		□ Persistent or Significant Disability or Incapacity		
		□ Other Serious Consequences		

6) Outcome of Adverse Event *

Actual Status of Patient	□ Recovered		
	□ Recovered with Sequelea	**Specify Sequelea**	
	□ Is Recovering		
	□ No Improvement		
	□ Fatal		
	□ Unknown		

In case you suspect ONE medicine, please answer the below question. If you suspect more than one medicine, please use the free text to describe the dechallenge corrective treatment and rechallenge, if applicable

Event subsided after stopping the medicine (Dechallenge)?	□ Yes □ No □ Unknown
Specific antagonist used/ Corrective treatment?	□ Yes / Specify: □ No □ Unknown
Event reappeared after reintroducing the medicine (Rechallenge)?	□ Yes □ No □ Unknown
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	□ Yes □ No □ Unknown

7) Possible Cause(s) of Adverse Event

Questions	Yes	No
If medicine, can the Adverse Event be due to:		
○ **Adverse Drug Reaction(s)**	□ Yes	□ No
○ **Abuse or Misuse of Medicine(s)**	□ Yes	□ No
○ **Interaction of Medicines**	□ Yes	□ No
○ **Medication(s) Error(s)**	□ Yes	□ No
○ **Lack of Efficacy of Medicine(s)**	□ Yes	□ No
○ **Defection in Medicine(s) Quality**	□ Yes	□ No
if vaccine, can the Adverse Event Following Immunization be due to:		
○ **Vaccine Product-Related Reaction**	□ Yes	□ No
○ **Vaccine Quality Defect Reaction**	□ Yes	□ No
○ **Immunization Error-Related Reaction**	□ Yes	□ No
○ **Immunization Anxiety-Related Reaction**	□ Yes	□ No
○ **Coincidental Event**	□ Yes	□ No

8) Did the patient have a similar reaction to the same or similar medicines, vaccines in any previous exposure? *

□ Yes/ Specify:	□ No	□ Unknown
Additional Note		
Tell us more about any extra relevant information/complementary investigation not mentioned in the previous questions		

9) Reporter *

Who are you?	**Patient / Consumer** □	**Health Care Professional** □ Specify:	**Responsible Party of Pharmaceutical Products** □	**Drug Distributor** □	**Others (Patient's Relatives, Neighbors, etc.)** □
Name (or initials)					
Profession or Specialty					
Professional Address					
Email Address					
Phone Number					

Signature	
Date	

10) Treating Physician (if applicable)	
Name (or initials)	
Specialty	
Professional Address	
Email Address	
Phone Number	
Signature	
Date	

Please send the completed form filled electronically or manually to the following email: pv@moph.gov.lb or phvg.phar@ul.edu.lb

For any additional information, you may contact 01/830255 or 01/830254