Quality Management System



## Adverse Event Reporting Form for Medicines & Vaccines



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Image: Single port         Image:		Reporter, patient & institution identities will remain confidential Questions with an asterisk(*) sign are mandatory																
Name (or initials)         Gender			🗆 Fii	rst Repo				Follow Up Report										
Omale         Omale <th< td=""><td>1) I</td><td>Patient De</td><td>tails *</td><td>:</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	1) I	Patient De	tails *	:														
Date of birth			Name	(or initia	als)													
Date of birth ge at onset       Image at onset	Gender				□ Male		□ Female											
Age at onset       Image: Construction of the section of the sectin of the section of the section of the section of the section of	Da	te of birth			Wai	aht (ka)												
□       □	Ag	ge at onset			wei	gnt (kg)		Height (cm)										
Smoker       Supplement/Specify:       Other medical condition/Specify:         Alcohol intake       Allergy/Specify:       Other medical condition/Specify:         Occasional - Frequent       Allergy/Specify:       Other medical condition/Specify:         3) Product(s) Details *       Medicine (s)       Started on Mana (s)       Stopped on Mana (s)         Medicine (s)       Batch       Expiry       Dose, Pose, P	2) I	Risk Facto	rs *									-						
Occasional □ Frequent         □ Supplement/ Specify:         □ Other medical condition/ Specify:           □ Occasional □ Frequent         □ Allergy/ Specify:         □ Other medical condition/ Specify:           3) Product(s) Details *         Wedicine (s)         Batch         Dose, Prequence, Dose, Prequence, Radministration         Started on         Stopped on           Medicine (s)         Mane + Use         Indication         Off Label         Batch         Dose, 			Renal	disease				Hepatic dise	ease					ardiac	e disease			
□ Alcohol intake       □ Allergy/ Specify:       □ Other medical condition/ Specify:         □ Other medical condition/ Specify:       □ Other medical condition/ Specify:         3) Product(s) Details *         Medicine (s)       Batch       Expiry Date       Dose, Prequenty, Date       Started on       Stopped on         Active Ingredient       Indication       Off Label Use       Batch       Expiry Date       Dose, Prequency, Date       Started on       Stopped on         (000000000000000000000000000000000000					uent		□ Su	oplement/ Sp	pecify:									
Occasional      Frequent      Occasional      Frequent      Occasional      Frequent      Occasional      Frequent      Occasional      Frequent      Occasional      Frequent      Off     S      Off     Dase     Frequency,     Dase     Frequency,     Dase     Frequency,     Dase     Started on     Stopped on     S      Outo of      Administration      Day     Month     Year     Year							A	llergy/ Sne	cify:			□ O	ther medi	cal co	ondition/	Spee	cify:	
Medicine (s)         Brand Name + Active Ingredient       Indication       Off Label Use       Batch Number       Expiry Date       Dose, Frequency, Dosage Form & Route of Administration       Started on       Stopped on         0900000000000000000000000000000000000					lent			linergy oper	y .									
Medicine Brand Active Ingredient     Indication     Off Label Use     Batch Number     Expiry Date     Dose, Frequency, Dosage Form & Route of Administration     Started on     Stopped on       09     Indication     Indication     Indication     Indication     Indication     Indication     Indication       1     Indication     Indication     Indication     Indication     Indication     Indication     Indication       1     Indication     Indication     Indication     Indication     Indication	3) F	Product(s)	Detai	ils *														
Brand Active Ingredient     Indication     Off Label Use     Batch Number     Expiry Date     Frequency, Date of Administration     Started on     Stopped on       000000000000000000000000000000000000	Me	dicine(s)																
Day       Month       Year       Day       Month       Year         Day       Month       Year       Day       <		Brand Name + Active	Indic	ation	Label			Frequence Dosage For Route o	rm & f			Started o	n		s	topp	ed on	
Vaccine(s)	ie(s)	<u> </u>							-	Da	y	Month	Year		Day	M	onth	Year
Vaccine(s)	Medicir									Da	y	Month	Year		Day	М	onth	Year
Vaccine(s)	pected									Da	y	Month	Year		Day	M	onth	Year
Vaccine(s)	Sus								ŀ									
Vaccine(s) Health Facility / Vaccination Center Name & Address										Da	y	Month	Year		Day	M	onth	Year
Vaccine(s) Health Facility / Vaccination Center Name & Address	mitant ine(s)									Da	y	Month	Year		Day	M	onth	Year
Vaccine(s) Health Facility / Vaccination Center Name & Address	Conco Medic									Da	v	Month	Vear		Dav	M	onth	Year
Health Facility / Vaccination Center Name & Address									F		.,		- cur					
	Vac	cine(s)																
Image: Second state of the constraint of the cons	Hea	lth Facility	/ Vacci	nation C	Center Nar	me & Add	lress											
Date of LightDate of LightExpiry Date of LightDate of LightExpiry Date of LightDate of Light<		cine	te	ber	pu (	q	e	ion al)	ion				For Dilu	ient (	if applic	able	)	
		Name of Vac.	Expiry Date Batch Numbi Dose (1 <sup>4</sup> , 2 <sup>nd</sup> etc.) bate of Vaccination Vaccination Vaccination (IM, SC, Oral (IM, SC, Oral		Name of Diluent		Expiry I			Batch Number		of						

4) Adverse			dvers	e Event Medicin	Rep	orting	g For		or				Edit Da ecepti Ca /	PV-F-01 iion 1 ite of ion at PV enter / C2021 ge 2 / 5
Country of Oc In case of N														
Th case of N	vieurcin	e(s) use					Onset	Date		R	ecovery I	Date (if	'annli	cable)
	Suspecto	ed Adverse	Event		Da	v	Mor		Year		ay	Date (if applicable) Month Year		Year
									ical		3			
In case of V	laccine	(s) Use												
		(3) 030					Onset	Date		R	ecovery I	Date (if	annli	cable)
Suspected Ad	dverse E	vent Follow	ing Imn	unization	Tir		Day	Mont		Tim	e Da		Aonth	Year
Local React	tion (Red	ness. Swelli	ng)		(Hr, !	/fin)				(Hr, Mi	n) — —			
	Fever $\geq 38$													
	Allerg	у												
	Fatigu	e												
	Headac	he												
		ection Site												
	ebrileSei febrile Se													
	Absce													
	Sepsis	5												
Eı	ncephalo													
		Syndrome												
Thr	rombocyt	topenia												
	Anaphyl	axis												
0	Other/ Spe	ecify:		1										
Adverse Ever			e Narrat	ive (Develop	oment,	Sympton	ns, Man	agem	ent, etc.)					1
Relevant		tory and Di Performed	agnostic	Tests	Da	y	Mo	Da <sup>.</sup> nth	te	Year		]	Result	

· · · · ·						Π				
	Qu	ality Man	agement	System		QMS-PV-F-01				
•					60	Edition 1 Date of				
	Adverse	- Event F	Renarti	ng Form for		reception at P				
		/ledicines			America America America	Center				
		104101110				/ / / LNPVC2021				
						Page 3 / 5				
			1							
			Day	Month	Year					
			Day	Wonth	1 Cal					
5) Seriousness of	Adverse Event	*	1							
			If yes,	please indicate why						
			The Ad	lverse Event led to:						
				> (1		Date of death				
				Death		Cause of				
				life Threatening Situat	ion	death				
			Hospitalization							
Serious	$\Box$ Yes		-		Specify					
		□ No	□ F	Prolongation of Hospita	alization	additional				
						duration				
				Surgical Intervention						
			Congenital Anomaly							
			□ F	Persistent or Significant	t Disability or Incapacity					
			Other Serious Consequences							
6) Outcome of Adv	orso Evont *									
of outcome of Adv	eise Lvein									
				Recovered with S	Sequelea Spec					
				□ Is Recovering						
Actual Status of Patien	nt			□ No Improvement	:					
				🗆 Fatal						
				🗆 Unknown						
					_					
In case you suspect Of describe the dechallen					ore than one medicine, pl	ease use the free text t				
			-			□ Yes				
Event subsided after s	topping the medicir	ne (Dechallen	ge)?			□ No □ Unknown				
						□ Yes / Specify:				
Specific antagonist used/ Corrective treatment?						□ No				
						□ Unknown □ Yes				
Event reappeared after reintroducing the medicine (Rechallenge)?						□ No				
						□ Unknown □ Yes				

Was the reaction more severe when the dose was increased or less severe when the dose was decreased?

 $\square \ No$ 

 $\square$  Unknown

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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					
<ul> <li>Medication(s) Error(s)</li> </ul>	□ 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:	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					
o Immunization Anxiety-Related Reaction	□ Yes	□ No					
o 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	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					



## Adverse Event Reporting Form for Medicines & Vaccines



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Signature	
Date	
10) Treating Physi	ician (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: <u>pv@moph.gov.lb</u>or<u>phvg.phar@ul.edu.lb</u> For any additional information, you may contact <u>01/830255</u> or <u>01/830254</u>