REPORT N° 3

ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 VACCINES IN LEBANON

COVID-19 Vaccines - Lebanon

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February 14, 2021 to May 30, 2021

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EXECUTIVE SUMMARY

This executive summary provides an overview of Adverse Events Following Immunization (AEFIs) that were temporally associated (i.e., occurred after administration of the vaccine) to the four vaccines available in Lebanon during the mass campaign immunization between February 14, 2021 and May 30, 2021 (Pfizer BioNTech Vaccine, AstraZeneca Vaccine, Sputnik V Vaccine and Sinopharm Vaccine). According to the World Health Organization (WHO), an AEFI is any untoward medical occurrence that follows immunization and does not necessarily have a causal relationship with the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

The total number of registered persons on the national platform for the mass immunization with Covid-19 vaccines is 1,098,198.

837,817 doses of COVID-19 vaccines have been administered during the period of time covered by the report, out of which 553,740 persons received the first dose of COVID-19 vaccine (66%) and 284,077 persons received both doses of COVID-19 vaccine (34%). As a result, 25.9% of the total registered people on the national platform are fully immunized.

The doses were administered as stated below:
649,259 doses of Pfizer-BioNTech Vaccine (77.5 % of total doses of COVID-19 vaccines)
117,493 doses of AstraZeneca Vaccine (14.03 % of total doses of COVID-19 vaccines)
64,532 doses of Sputnik V Vaccine (7.7 % of total doses of COVID-19 vaccines)
6,533 doses of Sinopharm Vaccine (0.77 % of total doses of COVID-19 vaccines)

As per the COVID-19 vaccination dashboard provided by IMPACT platform on May 30, 2021

BACKGROUND

Within the scope of the AEFI surveillance related to the available COVID-19 Vaccines in Lebanon, the PharmacoVigilance (PV) Program established a procedure for the management of reported AEFIs. Vaccine recipients experiencing any AEFI post-immunization can report through one of the following means: 1214 Hotline call center, Impact Platform, Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting", Preventive Medicine department, or Epidemiology Surveillance Program at the MoPH.
All case reports are screened and validated for data completion. Incomplete or inconsistent case reports are followed-up directly with the initial reporter.

The case reports are classified as serious, follow-up or non-serious cases. The non-serious case reports are entered directly into the national web-based report management system: VigiFlow. Follow-up cases are reviewed and based on the type of AEFI reported and its outcome, they are classified either as serious or non-serious cases. The surveillance aims to establish a rigorous safety profile in regards to the COVID-19 Vaccines administered in Lebanon.

HIGHLIGHTS

- A total of 2,856 case reports/ 9,461 AEFIs were received following the administration of 837,817 doses of COVID-19 vaccines (Pfizer BioNTech, AstraZeneca, Sputnik V and Sinopharm) in Lebanon between the 14th of February and the 30th of May 2021.
This is equivalent to a reporting rate of 3.4 case reports/11.3 AEFIs per 1,000 doses administered.
This represents an increase of 1,055/4,565 of case reports/AEFIs in comparison with the previous report dated 14 February to 30 May, 2021.

- Out of the 2,856 case reports (Table 1):
  - 2,713 case reports were non-serious (95% of total case reports)
  - 94 case reports were follow-up cases (3.3% of total case reports), of which 9 case reports were important medical events (0.3 % of total case reports)
  - 49 case reports were serious (1.7% of total case reports)

- Of the total received AEFIs, the 5 most frequently reported AEFIs with the three vaccines were (Table 4):
  - General pain (45.8% of total reported AEFIs). This may correspond to body pain or joint pain
  - Injection site pain (40.1 % of total reported AEFIs)
  - Fatigue (38.8 % of total reported AEFIs)
  - Chills (34.8 % of total reported AEFIs)
  - Headache (34.2 % of total reported AEFIs)

- The most frequently reported AEFIs per vaccine were: (Tables 6, 8, 10, 11)
  - General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (42.0 % of the total reported AEFIs related to Pfizer-BioNTech Vaccine)
  - Fatigue was the most common adverse event following all other vaccines: 58.6 % of the total reported AEFIs related to AstraZeneca Vaccine, 63.6 % of the total reported AEFIs related to Sputnik V vaccine, and 40.0 % of the total reported AEFIs related to Sinopharm Vaccine.

REPORTING OVERVIEW

a. Global Analysis

Table 1. Summary of all case reports related to COVID-19 vaccines in Lebanon, February 14, 2021 to May 30, 2021

COVID-19 Vaccines	Pfizer-BioNTech		AstraZeneca		Sputnik V		Sinopharm		All combined	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%	COUNT	%
Total case reports	1,680		1,004		162		10		2,856	
Non serious case* reports	1,573	93.7%	972	96.8%	160	98.8%	8	80%	2,713	95%
Follow-up case** reports	68	4%	23	2.3%	2	1.2%	1	10%	94	3.3%
Serious case*** reports	39	2.3%	9	0.9%	0	0	1	10%	49	1.7%
Doses administered	649,259		117,493		64,532		6,533		837,817	
Total reporting rate per 1,000 doses administered	2.59		8.54		2.51		1.53		3.40	
Serious reporting rate per 1,000 doses administered	0.06		0.07		0		0.15		0.058	

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24)
** Non serious cases include expected local and systemic AEFIs resolved with no need for further follow up or investigation*
*** Follow-up cases include unexpected, but not yet serious AEFIs, local or systemic, resolved or not in the next 48 hours*
**** Serious cases are those who meet the WHO seriousness criteria (refer to technical notes)*

b. Demographics

Tables 2 and 3 present a summary of case reports related to the Covid-19 vaccines by age group, gender and reporter qualification

Table 2. Summary of all case reports related to the four COVID-19 vaccines by age group and gender in Lebanon, February 14, 2021 to May 30 2021

PATIENT	COUNT	PERCENTAGE
Female	1,810	63.4%
Male	1,044	36.5%
Unknown Sex	2	0.1 %
12- 17 years	1	0.03%
18 - 44 years	1,228	43.0 %
45 - 64 years	1,000	35.0 %
65 - 74 years	210	7.4 %
≥ 75 years	370	13.0%
Unknown Age	47	1.6 %

Note: Age represents the age at time of vaccination. Some case reports records may be missing date of birth or gender
Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24)

Table 3. Summary of all case reports related to the four COVID-19 vaccines by reporter qualification in Lebanon, February 14, 2021 to May 30, 2021

REPORTER QUALIFICATION	COUNT	PERCENTAGE
Physician	141	4.9 %
Pharmacist	178	6.2 %
Other Health Professional	258	9.0 %
Lawyer	5	0.2%
Consumer/Non Health Professional	2,274	79.6%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24)

c. Types of Adverse Events Following Immunization

An AEFI case report refers to a report received by the PV Program, which pertains to one individual vaccine recipient who has reported at least one adverse event after receiving one of the COVID-19 vaccines (i.e., temporally associated with the vaccine).
The tables below give an overview of the reported AEFIs.

c.i. Most reported AEFIs related to COVID-19 vaccines

Table 4. Number and percentage of reported AEFIs (top 30) by symptom preferred term (PT)* related to the four COVID-19 vaccines in Lebanon, February 14, 2021 to May 30, 2021

Reported preferred terms* (MedDRA)	COUNT	PERCENTAGE
PT: Pain	1,309	45.8%
PT: Injection site pain	1,146	40.1%
PT: Fatigue	1,108	38.8%
PT: Chills	993	34.8%
PT: Headache	976	34.2%
PT: Pyrexia	804	28.2%
PT: Nausea	412	14.4%
PT: Injection site swelling	252	8.8%
PT: Injection site erythema	205	7.2%
PT: Diarrhoea	174	6.1%
PT: Abdominal pain	171	6.0%
PT: Dyspnoea	148	5.2%
PT: Cough	123	4.3%
PT: Vomiting	101	3.5%
PT: Rash	100	3.5%
PT: Respiratory symptom	97	3.4%
PT: Dizziness	77	2.7%
PT: Myalgia	72	2.5%
PT: Arthralgia	66	2.3%
PT: Hypoaesthesia	61	2.1%
PT: Hypertension	59	2.1%
PT: Pain in extremity	56	2.0%
PT: Tachycardia	51	1.8%
PT: Back pain	45	1.6%
PT: Chest pain	40	1.4%
PT: Oropharyngeal pain	40	1.4%
PT: Hyperhidrosis	28	1.0%
PT: Asthenia	25	0.9%
PT: Hypoaesthesia oral	24	0.8%
PT: Bone pain	21	0.7%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0).
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 5. Number and percentage of reported AEFIs by System Organ Class (SOC)* related to the four COVID-19 vaccines in Lebanon, February 14, 2021 to May 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	14	0.5%
SOC: Cardiac disorders	67	2.3%
SOC: Ear and labyrinth disorders	28	1.0%
SOC: Eye disorders	35	1.2%
SOC: Gastrointestinal disorders	647	22.7%
SOC: General disorders and administration site conditions	2,433	85.2%
SOC: Immune system disorders	12	0.4%
SOC: Infections and infestations	23	0.8%
SOC: Injury, poisoning and procedural complications	16	0.6%
SOC: Investigations**	36	1.3%
SOC: Metabolism and nutrition disorders	8	0.3%
SOC: Musculoskeletal and connective tissue disorders	258	9.0%
SOC: Nervous system disorders	1,107	38.8%
SOC: Psychiatric disorders	14	0.5%
SOC: Renal and urinary disorders	5	0.2%
SOC: Reproductive system and breast disorders	12	0.4%
SOC: Respiratory, thoracic and mediastinal disorders	241	8.4%
SOC: Skin and subcutaneous tissue disorders	163	5.7%
SOC: Surgical and medical procedures	1	0.0%
SOC: Vascular disorders	95	3.3%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**System Organ Classes (SOCs) are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures)*
*** Investigations include cases of increased blood pressure, decreased oxygen saturation, increased heart rate, polymerase chain reaction positive and cases who tested positive for SARS COVID 1 and 2.*

c.ii. Non-serious AEFIs

Table 6. Number and percentage of reported AEFIs (top 10) by symptom preferred term (PT)* related to Pfizer BioNTech COVID-19 vaccine in Lebanon, February 14, 2021 to May 30, 2021

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Pain	705	42.0%
PT: Injection site pain	522	31.1%
PT: Chills	448	26.7%
PT: Fatigue	413	24.6%
PT: Headache	395	23.5%
PT: Pyrexia	304	18.1%
PT: Nausea	159	9.5%
PT: Injection site swelling	151	9.0%
PT: Injection site erythema	124	7.4%
PT: Diarrhoea	76	4.5%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 7. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Pfizer BioNTech Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	10	0.6%
SOC: Cardiac disorders	53	3.2%
SOC: Ear and labyrinth disorders	18	1.1%
SOC: Eye disorders	14	0.8%
SOC: Gastrointestinal disorders	281	16.7%
SOC: General disorders and administration site conditions	1,352	80.5%
SOC: Immune system disorders	7	0.4%
SOC: Infections and infestations	15	0.9%
SOC: Injury, poisoning and procedural complications	4	0.2%
SOC: Investigations**	26	1.5%
SOC: Metabolism and nutrition disorders	5	0.3%
SOC: Musculoskeletal and connective tissue disorders	144	8.6%
SOC: Nervous system disorders	467	27.8%
SOC: Psychiatric disorders	8	0.5%
SOC: Renal and urinary disorders	3	0.2%
SOC: Reproductive system and breast disorders	4	0.2%
SOC: Respiratory, thoracic and mediastinal disorders	124	7.4%
SOC: Skin and subcutaneous tissue disorders	77	4.6%
SOC: Surgical and medical procedures	1	0.1%
SOC: Vascular disorders	59	3.5%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**System Organ Classes (SOCs) are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures)*
*** Investigations include cases of increased blood pressure, decreased oxygen saturation and cases who tested positive for SARS COVID 1 and 2.*

Table 8. Number and percentage of reported AEFIs (top 10) by symptom preferred term (PT)* related to AstraZeneca COVID-19 Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	588	58.6%
PT: Injection site pain	546	54.4%
PT: Pain	519	51.7%
PT: Headache	506	50.4%
PT: Chills	468	46.6%
PT: Pyrexia	437	43.5%
PT: Nausea	216	21.5%
PT: Abdominal pain	93	9.3%
PT: Injection site swelling	93	9.3%
PT: Diarrhoea	82	8.2%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 9. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to AstraZeneca COVID-19 Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	3	0.3%
SOC: Cardiac disorders	13	1.3%
SOC: Ear and labyrinth disorders	8	0.8%
SOC: Eye disorders	20	2.0%
SOC: Gastrointestinal disorders	317	31.6%
SOC: General disorders and administration site conditions	924	92.0%
SOC: Immune system disorders	5	0.5%
SOC: Infections and infestations	5	0.5%
SOC: Injury, poisoning and procedural complications	12	1.2%
SOC: Investigations**	10	1.0%
SOC: Metabolism and nutrition disorders	3	0.3%
SOC: Musculoskeletal and connective tissue disorders	105	10.5%
SOC: Nervous system disorders	558	55.6%
SOC: Psychiatric disorders	6	0.6%
SOC: Renal and urinary disorders	2	0.2%
SOC: Reproductive system and breast disorders	7	0.7%
SOC: Respiratory, thoracic and mediastinal disorders	99	9.9%
SOC: Skin and subcutaneous tissue disorders	72	7.2%
SOC: Vascular disorders	34	3.4%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**System Organ Classes (SOCs) are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures)*
*** Investigations include cases of increased blood pressure, increased heart rate, polymerase chain reaction positive and cases who tested positive for SARS COVID 1 and 2.*

Table 10. Number and percentage of reported AEFIs (top 10) by symptom preferred term (PT)* related to Sputnik V Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	103	63.6%
PT: Pain	83	51.2%
PT: Chills	76	46.9%
PT: Injection site pain	75	46.3%
PT: Headache	73	45.1%
PT: Pyrexia	62	38.3%
PT: Nausea	34	21.0%
PT: Diarrhoea	15	9.3%
PT: Abdominal pain	10	6.2%
PT: Cough	10	6.2%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 11. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Sputnik V Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	1	0.6%
SOC: Ear and labyrinth disorders	2	1.2%
SOC: Gastrointestinal disorders	46	28.4%
SOC: General disorders and administration site conditions	150	92.6%
SOC: Infections and infestations	3	1.9%
SOC: Musculoskeletal and connective tissue disorders	9	5.6%
SOC: Nervous system disorders	78	48.1%
SOC: Reproductive system and breast disorders	1	0.6%
SOC: Respiratory, thoracic and mediastinal disorders	16	9.9%
SOC: Skin and subcutaneous tissue disorders	14	8.6%
SOC: Vascular disorders	2	1.2%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**System Organ Classes (SOCs) are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures)*

Table 12. Number and percentage of reported AEFIs (top 10) by symptom preferred term (PT)* related to Sinopharm Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Reported preferred terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	4	40.0%
PT: Injection site pain	3	30.0%
PT: Nausea	3	30.0%
PT: Chest pain	2	20.0%
PT: Dyspnoea	2	20.0%
PT: Headache	2	20.0%
PT: Pain	2	20.0%
PT: Vomiting	2	20.0%
PT: Chills	1	10.0%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 13. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Sinopharm Vaccine in Lebanon, February 14, 2021 to May 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Eye disorders	1	10.0%
SOC: Gastrointestinal disorders	3	30.0%
SOC: General disorders and administration site conditions	7	70.0%
SOC: Nervous system disorders	4	40.0%
SOC: Respiratory, thoracic and mediastinal disorders	2	20.0%

Data Source: VigiLyze (Dataset date: 30/05/2021, MedDRA version: 24.0)
**System Organ Classes (SOCs) are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures)*

iii. Follow-up AEFIs

Table 14. Number and percentage of reported follow-up AEFIs by symptoms preferred term (PT)* related to Pfizer BioNTech COVID-19 vaccine in Lebanon, February 14, 2021 to May 30, 2021

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NOT SERIOUS)
Medical Events that Require Close Monitoring**	PT: Hypertension	23	33.8%	64	4.0%	Recovered	Not Serious
	PT: Chills	16	23.5%				
	PT: Injection site pain	13	19.1%				
	PT: Rash	13	19.1%				
	PT: Tachycardia	13	19.1%				
	PT: Fatigue	12	17.6%				
	PT: Pain	12	17.6%				
	PT: Headache	10	14.7%				
	PT: Dyspnoea	9	13.2%				
	PT: Nausea	9	13.2%				
	PT: Pyrexia	7	10.3%				
	PT: Hypotension	6	8.8%				
	PT: Vomiting	5	7.4%				
	PT: Dizziness	4	5.9%				
	PT: Abdominal pain	3	4.4%				
	PT: Cough	3	4.4%				
	PT: Injection site rash	3	4.4%				
	PT: Urticaria	3	4.4%				
	PT: Chest discomfort	2	2.9%				
	PT: Hyperventilation	2	2.9%				
	PT: Hypoaesthesia	2	2.9%				
	PT: Influenza like illness	2	2.9%				
	PT: Injection site erythema	2	2.9%				
	PT: Laryngospasm	2	2.9%				
	PT: Contusion	2	2.9%				
	PT: Respiratory symptom	2	2.9%				
	PT: SARS-CoV-2 test positive	2	2.9%				
	PT: Abdominal pain upper	1	1.5%				
	PT: Burning sensation	1	1.5%				
	PT: Chest pain	1	1.5%				
	PT: Diarrhoea	1	1.5%				
	PT: Ecchymosis	1	1.5%				
	PT: Granuloma	1	1.5%				
	PT: Hyperhidrosis	1	1.5%				
	PT: Hypersensitivity	1	1.5%				
	PT: Hypoglycaemia	1	1.5%				
	PT: Muscle rigidity	1	1.5%				
	PT: Muscle spasms	1	1.5%				
	PT: Myalgia	1	1.5%				
	PT: Oedema	1	1.5%				
	PT: Pain in extremity	1	1.5%				
	PT: Panic attack	1	1.5%				
	PT: Pruritus	1	1.5%				

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NOT SERIOUS)
Medical Events that Require Close Monitoring**	PT: Rash popular	1	1.5%				
	PT: Thrombophlebitis	1	1.5%				
	PT: Vasculitis	1	1.5%				
	PT: Vertigo	1	1.5%				
	PT: Injection site swelling	1	1.5%				
	PT: Hypoaesthesia oral	1	1.5%				
	PT: Decreased appetite	1	1.5%				
	PT: Oropharyngeal pain	1	1.5%				
	PT: Injection site hypoaesthesia	1	1.5%				
Important Medical Events***	PT: Atypical pneumonia	1	1.5%	4			
	PT: Facial paralysis	1	1.5%				
	PT: Bell's palsy	1	1.5%				
	PT: Angioedema	1	1.5%				

Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*
***Medical Events that require close monitoring are not included in the EMA Important Medical Events terms list, yet they are considered as important AEFIs within the PV Program. Some AEFIs such as chills, fatigue, dizziness and headache are non-serious however co-reported with AEFIs that require follow-up.*
****Important Medical Events are defined by the EMA Important Medical Events terms list MedDRA version: 24 (refer to technical notes)*

Table 15. Number and percentage of reported follow-up AEFIs by symptoms preferred term (PT)* related to AstraZeneca COVID-19 vaccine in Lebanon, February 14, 2021 to May 30, 2021

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NOT SERIOUS)
Medical Events that Require Close Monitoring**	PT: Headache	13	56.5%	19	2.3%	Recovered	Not Serious
	PT: Chills	8	34.8%				
	PT: Fatigue	8	34.8%				
	PT: Injection site pain	8	34.8%				
	PT: Hypertension	7	30.4%				
	PT: Tachycardia	6	26.1%				
	PT: Pyrexia	5	21.7%				
	PT: Hypotension	4	17.4%				
	PT: Nausea	4	17.4%				
	PT: Pain	4	17.4%				
	PT: Contusion	4	17.4%				
	PT: Injection site swelling	4	17.4%				
	PT: Abdominal pain	3	13.0%				
	PT: Chest pain	3	13.0%				
	PT: Diarrhoea	3	13.0%				
	PT: Bone pain	2	8.7%				
	PT: Dyspnoea	2	8.7%				
	PT: Myalgia	2	8.7%				
	PT: Paraesthesia	2	8.7%				
	PT: Rash	2	8.7%				
	PT: Hypoaesthesia oral	2	8.7%				
	PT: Arthralgia	1	4.3%				
	PT: Axillary vein thrombosis	1	4.3%				
	PT: Discomfort	1	4.3%				

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NOT SERIOUS)
	PT: Dizziness	1	4.3%				
	PT: Ear pain	1	4.3%				
	PT: Eructation	1	4.3%				
	PT: Feeling hot	1	4.3%				
	PT: Gingival pain	1	4.3%				
	PT: Hyperhidrosis	1	4.3%				
	PT: Hypersensitivity	1	4.3%				
	PT: Influenza like illness	1	4.3%				
	PT: Injection site erythema	1	4.3%				
	PT: Lacrimation increased	1	4.3%				
	PT: Lymphadenopathy	1	4.3%				
	PT: Muscle spasms	1	4.3%				
	PT: Pain in extremity	1	4.3%				
	PT: Palpitations	1	4.3%				
	PT: Snoring	1	4.3%				
	PT: Swelling face	1	4.3%				
	PT: Tinnitus	1	4.3%				
	PT: Vision blurred	1	4.3%				
	PT: Limb discomfort	1	4.3%				
	PT: Oropharyngeal pain	1	4.3%				
	PT: Respiratory symptom	1	4.3%				
Important Medical Events***	PT: Syncope	3	13.0%	4			
	PT: Bell's palsy	1	4.3%				

Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*
***Medical Events that require close monitoring are not included in the EMA Important Medical Events terms list, yet they are considered as important AEFIs within the PV Program. Some AEFIs such as chills, fatigue, dizziness and headache are non-serious however co-reported with AEFIs that require follow-up.*
****Important Medical Events are defined by the EMA Important Medical Events terms list MedDRA version: 24 (refer to technical notes)*

Table 16. Number and percentage of reported follow-up AEFIs by symptoms preferred term (PT)* related to Sputnik V vaccine in Lebanon, February 14, 2021 to May 30, 2021

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NOT SERIOUS)
Medical Events that Require close Monitoring**	PT: Dyspnoea	2	100.0%	1	1.2%	Recovered	Not Serious
	PT: Hypotension	2	100.0%				
Important Medical Events***	PT: Chest pain	1	50.0%	1			
	PT: Syncope	1	50.0%				

Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*
***Medical Events that require close monitoring are not included in the EMA Important Medical Events terms list.*
****Important Medical Events are defined by the EMA Important Medical Events terms list MedDRA version: 24 (refer to technical notes)*
N.B: In the above presented cases, more than one AEFI was seen in the same case

Table 17. Number and percentage of reported follow-up AEFIs by symptoms preferred term (PT)* related to Sinopharm COVID-19 vaccine in Lebanon, February 14, 2021 to May 30, 2021

	Reported preferred terms (MedDRA)	COUNT	PERCENTAGE	NUMBER OF CASE REPORTS	PERCENTAGE OF TOTAL CASE REPORTS	OUTCOME	FINAL CLASSIFICATION (SERIOUS/ NON SERIOUS)
Medical Events that Require Close Monitoring**	PT: Chest pain	1	100.0%	1	10%	Recovered	Non Serious
	PT: Pain	1	100.0%				
	PT: Paraesthesia	1	100.0%				

Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24)
**Preferred Terms (PTs), are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*
***Medical Events that require close monitoring are not included in the EMA Important Medical Events terms list.*

d. Overview of Serious Cases:

AEFIs are classified as serious according to the seriousness criteria of WHO (refer to the technical notes). These cases either require a phone call or an investigation followed by a causality assessment in order to evaluate the potential relationship between the AEFI and the vaccine and to implement the appropriate actions.

Table 18: Summary of 44* serious cases by gender, age groups, dose number and time of AEFI occurrence

18 SUSPECTED DEATH CASES								
Gender		Age Groups				Dose		Time of death
Males	Females	>75	65-74	45-64	18-44	1st	2nd	
10	8	12	1	3	2	12	6	Between 20 minutes to 20 days post vaccination

26 HOSPITALIZED CASES								
Gender		Age Groups				Dose		Time of AEFI's onset
Males	Females	>75	65-74	45-64	18-44	1st	2nd	
6	20	12	3	4	7	18	8	Between 1 day to 21 days post vaccination

**The total serious case repots is 49. (5) reports had incomplete data that hindered the completion of their assessment and consequently were not included in the report.*

Table 19: Summary of all 44* Serious cases per Vaccine:

Serious Cases	All vaccines combined	Pfizer-BioNTech	Astra Zeneca	SPUTNIK V	SINOPHARM
Death	18	14	3	0	1
Hospitalized with onsite investigation	15	13	2	0	0
Hospitalized with follow up/investigation over the phone	11	10	1	0	0
TOTAL	44	37	6	0	1

**The total serious case repots is 49. (5) reports had incomplete data that hindered the completion of their assessment and consequently were not included in the report.*

Table 20: Status of the 44 Serious Cases

Serious Cases		AEFI Committee Assessment		AEFI Committee Final Decision	
Status	**All vaccines combined**	**Completed**	**In progress/ Under assessment***	**No Causal relationship**	**In progress/ Under assessment***
Death	18	5	13	5	13
Hospitalized with onsite investigation	15	7	8	7	8
TOTAL	33	12	21	12	21
Hospitalized with follow up/investigation over the phone	11	NA**	NA**	NA**	NA**

**In progress/Under assessment: these are case reports that have been investigated and are currently being evaluated by the members of the Serious AEFI Committee.*
***NA: Case reports that are followed up by the phone calls only without the need for any further investigations*

DESCRIPTION OF ADVERSE EVENTS FOLLOWING IMMUNIZATION

The age group of vaccine recipients who mostly reported AEFIs was 18 to 44 years old (43%), with females reporting more AEFIs than males (63.4% vs. 36.5%) (Table 2). The majority of the reporters were the vaccine recipients.

The most reported AEFIs for all COVID-19 vaccines per symptom were general pain (45.8% of total reported AEFIs), injection site pain (40.1 % of total reported AEFIs), Fatigue (38.8% of total reported cases) and chills (34.8 % of total reported AEFIs) (Table 4).

The most reported AEFIs by System Organ Class were general disorders and administration site conditions (85.2% of total reported AEFIs per SOC), followed by nervous system disorders (38.8 % of total reported AEFIs per SOC), and gastrointestinal disorders (22.7 % of total reported AEFIs per SOC) (Table 5).

General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (42 % of total reported AEFIs related to Pfizer-BioNTech Vaccine). Fatigue was the most common adverse event following all other vaccines: 58.6 % of the total reported AEFIs related to AstraZeneca Vaccine, 63.6 % of the total reported AEFIs related to Sputnik V Vaccine, and 40 % of the total reported AEFIs related to Sinopharm Vaccine. (Tables 6, 8, 10 and 12).

AEFIs are classified as serious, follow-up or non-serious.

Non serious AEFIs

Non serious AEFIs are benign, expected local and systemic AEFIs that are resolved without further follow-up nor investigation. The most commonly reported non-serious AEFIs with the COVID-19 vaccines are listed under (c.ii.).

Follow-up AEFIs

Follow-up AEFIs are unexpected, local or systemic adverse events that are of concern and require special consideration, however do not fulfill the WHO seriousness criteria (refer to technical notes). Depending on their type, follow-up AEFIs are divided into "important medical events" based on the EMA list (refer to technical notes) or medical events "requiring close monitoring" if they are not part of the EMA list. These cases require close surveillance by the PV Program. Such types of events may jeopardize the vaccine recipient or may require intervention to prevent an outcome described in the WHO seriousness criteria. Based on its outcome, a follow up AEFI may be reclassified as serious.

Among the follow-up AEFIs, the most reported AEFIs that required close monitoring were: *(Tables 14, 15, 16, and 17).*

- Hypertension (23 case reports), Tachycardia (13 case reports), Dyspnea (9 case reports), Hypotension (6 case reports), Contusion/Echymosis (3 case reports) for Pfizer BionNTech Vaccine.
- Headache (13 case reports), Hypertension (7 case reports), Tachycardia (6 case reports), Contusion (4 case reports), Dyspnea (2 case reports), and Axillary Vein Thrombosis (1 case report) for AstraZeneca Vaccine.
- Dyspnea and Hypotension (2 case reports each) for Sputnik V Vaccine.
- Chest pain and Paresthesia (one case report) for Sinopharm Vaccine.

Among the follow-up AEFIs, the most reported important medical events as per the EMA list (refer to technical notes) were:

- Atypical pneumonia, facial paralysis, and Angioedema (1 case report each) for Pfizer BioNTech Vaccine.
- Bell's Palsy (one case report) for Pfizer BioNTech Vaccine and (1 case report) for AstraZeneca vaccine.
- Syncope (1 case report) for Sputnik V Vaccine and (1 case report) for AstraZeneca Vaccine.

All follow-up cases were resolved, therefore not reclassified as serious.

It is worth noting that some of reported AEFIs are sometimes automatically converted by Vigiflow into their preferred term of reporting. In our cases, all cases of bruising were reported as contusion by the Vigylze system. Cases of headache post AstraZeneca Vaccine were followed up to rule out any other serious AEFI such bleeding or ischemic CVA.

Serious AEFIs

AEFIs are classified as serious according to the seriousness criteria of WHO (refer to the technical notes). These cases either require a phone call or an investigation followed by a causality assessment in order to evaluate the potential relationship between the AEFI and the vaccine and to implement the appropriate follow-up actions. The investigation is carried out by the PV Program and includes an extensive and rigorous scientific evaluation with a vaccination site visit, access to vaccine recipient's medical reports and laboratory results, and questioning concerned recipient or his/her relatives. After collecting all available information, the investigation report is filled and a causality assessment is performed by a group of experts in order to review the potential causal association between the AEFI and vaccine. WHO forms and tools are used to carry out both the investigation and the causality assessment. Findings are discussed with the Serious AEFI Special Committee at Ministry of Public Health (MoPH) stated by Ministerial Decision N°603.

In the period of time covered by this report, there were 49 case reports classified as serious, representing 1.7% of all case reports and a serious AEFI reporting rate of 0.058 per 1,000 doses of vaccines. Of the 49 cases, there were 5 reports who were missing essential information and their investigation is still pending. As for the remaining 44 case reports, there were 11 reports that were followed up by the phone only without the need for further investigation. The remaining 33 cases all required close follow up with investigation and causality assessment, out of these cases, 12 cases have been already assessed by the Serious AEFI Special Committee at Ministry of Public Health and a final decision was concluded with the agreement of all members. (Table 20)

Overview of all serious cases

Out of the 44 total reported cases, there are 18 cases of suspected death post vaccine, and 26 cases of hospitalization.
For the 26 hospitalized cases post vaccination, (6 Males: 20 Females), the vaccines' recipients age was as follows: 12 cases were above 75 years, 3 cases were between 65 and 74, 4 cases were between 45 and 64, and 7 cases were between 18 and 44 years old. 18 hospitalization occurred post dose 1, while the remaining 8 hospitalization occurred post dose 2. The 26 vaccine recipients experienced AEFIs within one day to 21 days post vaccination. (Tables 18 and 19)
In the 18 death cases, (10 Males: 8 Females), the vaccines' recipients age was as follows: 12 cases were above 75 years,1 case was between 65 and 74, 3 cases were between 45 and 64, and 2, cases were between 18 and 44 years old. 12 death cases were post dose one while the remaining 6 cases were post dose 2. The 18 vaccine recipients experienced AEFIs within 20 minutes to 20 days post vaccination. (Tables 18 and 19)

Update on the serious cases from previous reports:

Eight cases were followed up by the phone only and did not require any further investigation. All of these were discharged from the hospital and recovered.

Thirteen hospitalized old cases were investigated and followed up with complete causality assessment. All 13 cases have been discharged from the hospital with full recovery. Out of these 13 cases, 7 cases were assessed by the Serious AEFI Special Committee at the Ministry of Public Health (MoPH) and confirmed the coincidental relation with the vaccine. (Tables 19 and 20)
Twelve death cases investigation was completed with causality evaluation. Out of which, 5 cases were assessed by the Serious AEFI Special Committee at Ministry of Public Health (MoPH) and confirmed the coincidental relation with the vaccine. (Tables 19 and 20)

New Serious Cases:

Three cases were hospitalized but were followed up by the phone only and did not require any further investigation:

- One case of Myocardial infarction, second day post first dose of Pfizer BioNetch. The patient was discharged from the hospital and completely recovered.
- One case of Syncope, one-hour post first dose of AstraZeneca vaccine. The patient was discharged from the hospital and completely recovered.
- One case of PCR positive, 16 days post first dose of AstraZeneca vaccine. The patient improved and is recovering.

Two new cases were hospitalized and required in-depth investigation with causality assessment:

The two case reports are related to the SOC “Nervous System Disorder”.

- One Bleeding CVA case post first dose of AstraZeneca vaccine. The patient is a healthy 55 years old female. The AEFI occurred 5 days post vaccination. Patient was discharged from the hospital and is still under recovery.
- The second reported case is a Stroke case post first dose of Pfizer BioNTech Vaccine. The patient is 74 Years Old Male with hypertension and diabetes. The AEFI occurred 21 days post vaccination. Patient is still at the hospital.

The investigation and causality assessment of both cases are not yet finalized; the results will be reviewed by the Serious AEFI Special Committee at MoPH once the investigation is completed.

Six cases resulted in death post vaccination. The vaccine recipients were between 30 and 75 years old. The investigation and causality assessment have not yet been finalized. (Tables 18, 19, 20)

COMPARISON WITH INTERNATIONAL AEFI DATA

The most frequently reported AEFIs in the WHO UMC global database (Vigibase) in regard to the four COVID-19 vaccine described in this report were Headache (21.8 % of total reported AEFIs), Pyrexia (15.4 % of total reported AEFIs), Fatigue (15.0 % of total reported AEFIs), Chills (12.6 % of total reported AEFIs), and Dizziness (12.1 % of total reported AEFIs). The results are compatible with the national data which include Fatigue, Chills, Headache, and Pyrexia in the top 10 most reported AEFIs in Lebanon (Table 4).

In regards to signals (refer to technical notes) associated with the AEFIs by Pfizer BioNTech and AstraZeneca Vaccine:

In France, the ANSM has highlighted several potential and confirmed signals, with both vaccines, Pfizer BioNTech and AstraZeneca.

In Lebanon, the below reported AEFIs during the time of this report, may be considered as potential or confirmed signals for both vaccines, Pfizer BioNTech and AstraZeneca, which are aligned with the ANSM signal list:

For Pfizer BioNTech Vaccine:

- The **potential** signals include: Tachycardia/ Atrial Fibrillation/ palpitation (43 reported AEFIs), Spontaneous hematoma, manifested by our reported AEFI as contusion (3 case reports).
- The **confirmed** signals include: Hypertension/increased blood pressure (50 reported AEFIs).

For AstraZeneca Vaccine:

- The **potential** signal includes: Hypertension/increased blood pressure (21 reported AEFIs), bruising/hematoma/Epistaxis/oral bruising/ vaginal bleeding (15 reported AEFIs), Influenza like syndrome/Dyspnea with influenza (17 reported AEFIs), Bell's palsy (one case report).
- The **confirmed** signals include: Thrombosis/Axillary Vein thrombosis/ CVA (3 reported AEFIs).

The WHO UMC Vigibase has highlighted Trigeminal Neuralgia (refer to technical notes) and hearing loss/Tinnitus as confirmed signals with both, Pfizer BioNTech and AstraZeneca vaccines.

In Lebanon, both vaccines have reported AEFIs that may be considered as associated potential signals:

- **Pfizer BioNTech Vaccine:** Paresthesia (14 reported AEFIs), Hypoesthesia oral (14 reported AEFIs), paresthesia oral (4 reported AEFIs), Hypoesthesia (22 reported AEFIs), Eye pain (2 reported AEFIs), Ear pain (2 reported AEFIs), facial paralysis (one reported AEFIs), Facial pain (one reported AEFI), and Tinnitus (2 reported AEFIS).
- **AstraZeneca Vaccine:** Paresthesia (5reported AEFIs), Hypoesthesia oral (10 reported AEFIs), Hypoesthesia (37 reported AEFIs), Eye pain (2 reported AEFIs), Ear pain (3 reported AEFIs), jaw pain (2 reported AEFIs), and Tinnitus (2 reported AEFIS).

CONCLUSION

In the scope of the post-marketing surveillance conducted by the PV Program, a total of 2,856 case reports/ 9,461 AEFIs were received and analyzed following a total of 837,817 doses of COVID-19 vaccines (Pfizer BioNTech Vaccine, AstraZeneca Vaccine, Sputnik V Vaccine, and Sinopharm vaccine) administered in Lebanon from February 14th till 30th May 2021. This is equivalent to a reporting rate of 3.4 case reports/11.3 AEFIs per 1,000 doses administered. The IMPACT platform was the main mean of reporting. The vaccine recipients were the main reporters. The age group of vaccine recipients who mostly reported AEFIs was 18 to 44 years old, with females reporting more AEFIs than males. Most AEFIs reported on national basis are compatible with those reported on the international database. Trigeminal Neuralgia and Tinnitus, following vaccination with Pfizer BioNTech Vaccine and AstraZeneca Vaccine are potential signals. Hypertension and Thrombosis are confirmed signals following Pfizer BioNTech and AstraZeneca vaccines respectively.

The PV Program continues to conduct constant monitoring for the safety of COVID-19 vaccines in collaboration with its partners, including individual case review, daily analysis of surveillance data for vaccine safety signals and monthly reporting.

TECHNICAL NOTES

- Important medical event terms list: The EudraVigilance Expert Working Group (EV-EWG) has coordinated the development of an Important Medical Event Terms (IME, MedDRA version: 24.0) list. This IME list aims to facilitate the classification of suspected adverse reactions as well as aggregated data analysis and case assessment in the frame of the day-to-day PV activities of stakeholders. The IME list is intended for guidance purposes only.

- EudraVigilance is the system for managing and analyzing information on suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

- MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology, published by the International Council for Harmonization, used in particular for coding cases of adverse effects in clinical study reports and pharmacovigilance databases, and to facilitate searches in these databases.

- PIDM: The WHO Program for International Drug Monitoring (PIDM), established in 1968, provides a forum for WHO Member States to collaborate in the monitoring of drug safety, and notably, the identification and analysis of new adverse reaction signals from data submitted to the WHO global individual case safety report (ICSR) database by member countries.

- Seriousness criteria: According to the WHO, a serious AEFI is an event that results in death, hospitalization or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth, defect or is life-threatening or is a medically important event or reaction.

- Signal: According to the World Health Organization (WHO), a "signal" is a reported information on a possible causal relationship between an AE and a drug, the relationship being unknown or incompletely documented previously. Usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information.

- Trigeminal Neuralgia: is a neuropathic pain condition affecting the fifth cranial nerve and causing one of the most severe pains to be experienced. Symptoms include extreme, sporadic, sudden burning or shock like pain lasting from seconds up to two minutes and is usually unilateral.

- VigiFlow is a web-based individual case safety report (ICSR) management system that is available for use by national PV centers of the WHO Program for International Drug Monitoring.

- VigiBase is the WHO global ICSR database that contains ICSRs submitted by the participating member states enrolled under WHO's international drug monitoring program. It is the single largest drug safety data repository in the world.

- VigiLyze supports the collection, processing, and sharing of data of case reports to facilitate effective data analysis. VigiLyze is a signal detection and management system that can use national, regional or global data as the starting point for quantitative signal detection.

DATA CAVEATS

- Each case report refers to a reporter who reported an AEFI after receiving a dose of COVID-19 vaccine. A case report may contain multiple AEFIs. Therefore, the total number of AEFIs can exceed the number of individual case reports reported in a given time frame. Case reports that did not contain an AEFI at the time of data extraction or was missing the Vaccine name have been excluded.
- AEFI reporting rates were calculated using the number of vaccines' specific AEFIs reported in the specified time period in Lebanon divided by the doses of vaccines administered in the same time period in Lebanon.
- The information available in this report does not represent Uppsala Monitoring Center (UMC) nor WHO's opinions.

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