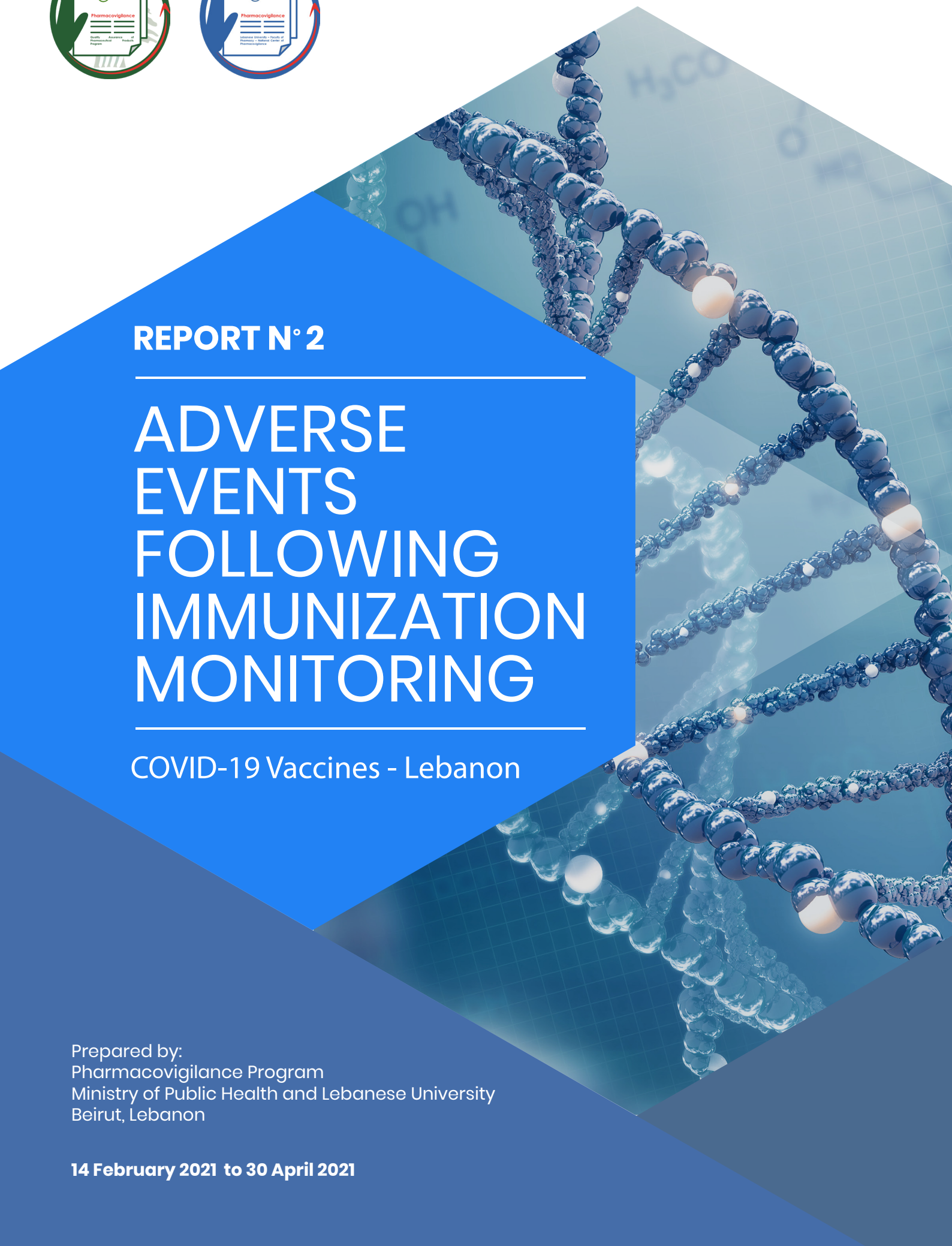

REPORT N° 2

ADVERSE EVENTS FOLLOWING IMMUNIZATION MONITORING

COVID-19 Vaccines - Lebanon

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Beirut, Lebanon

14 February 2021 to 30 April 2021

INDEX

MONTHLY 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 three vaccines available in Lebanon during the mass campaign immunization between February 14, 2021 and April 30, 2021 (Pfizer BioNTech Vaccine, AstraZeneca Vaccine and Sputnik V 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.

463,792 doses of COVID-19 vaccines have been administered during the period of time covered by the report. Out of 836,642 registered patients on the national platform, 278,635 patients received the first dose of COVID-19 vaccine (33.3%) and 185,157 patients received both doses of COVID-19 vaccine (22.1%).

The doses were administered as stated below:

401,468 doses of Pfizer-BioNTech Vaccine
(86.6% of total doses of COVID-19 vaccines)

38,897 doses of AstraZeneca Vaccine
(8.4% of total doses of COVID-19 vaccines)

22,357 doses of Sputnik V Vaccine
(4.8% of total doses of COVID-19 vaccines)

1,070 doses of Sinopharm Vaccine
(0.2% of total doses of COVID-19 vaccines)
Related AEFIs were not collected in the period of time covered by the report.

As per the COVID-19 vaccination dashboard provided by IMPACT platform on April 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 (refer to technical notes), Vaccination Sites/Hospital Sites, 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 1,801 case reports/4,896 AEFIs were received following the administration of 462,722 doses of COVID-19 vaccines (Pfizer BioNTech, AstraZeneca and Sputnik V) in Lebanon between 14th of February and 30th of April 2021. This is equivalent to a reporting rate of 3.9 case reports/10.6 AEFIs per 1,000 doses administered.
- Out of the 1,801 case reports (Table 1):
  - 1,708 case reports were non-serious (94.9% of total case reports)
  - 62 case reports were follow-up cases (3.4% of total case reports), of which 3 case reports were important medical events (0.2% of total case reports)
  - 31 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 (44.5% of total reported AEFIs)
  - Injection site pain (32.6% of total reported AEFIs)
  - Chills (31.4% of total reported AEFIs)
  - Fatigue (29.1% of total reported AEFIs)
  - Headache (28.2% of total reported AEFIs).
- The most frequently reported AEFIs per vaccine were:
  - General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (44.8% of the total reported AEFIs related to Pfizer-BioNTech Vaccine)
  - Fatigue was the most common adverse event following both AstraZeneca Vaccine (59.1% of the total reported AEFIs related to AstraZeneca Vaccine) and Sputnik V Vaccine (59.8% of the total reported AEFIs).

REPORTING OVERVIEW

a. Global Analysis

Table 1 presents a summary of case reports related to COVID-19 vaccines.

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

COVID-19 Vaccines	Pfizer-BioNTech		AstraZeneca		Sputnik V		All combined	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%
Total case reports	1435		283	97.5%	83		1801	
Non serious case* reports	1350	94%	276	2.5%	82	98.8%	1708	94.9%
Follow-up case** reports	54	3.8%	7	0%	1	1.2%	62	3.4%
Serious case*** reports	31	2.2%	0		0	0	31	1.7%
Doses administered	401,468		38,897		22,357		462,722	
Total reporting rate per 1,000 doses administered	3.6		7.3		3.7		3.9	
Serious reporting rate per 1,000 doses administered	0.07		0		0		0.07	

Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24.0)
** 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 COVID-19 vaccines by age group and gender in Lebanon, February 14, 2021 to April 30, 2021

PATIENT	COUNT	PERCENTAGE
Female	1,169	65%
Male	632	35%
18 - 44 years	847	47.1%
45 - 64 years	471	26.1%
65 - 74 years	96	5.3%
≥ 75 years	344	19.1%
Unknown	43	2.4%

Note: Age represents the age at time of vaccination. Some case reports records may be missing date of birth
Data Source: VigiLyze (Dataset date: 09/05/2021, MedDRA version: 24.0)

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

REPORTER QUALIFICATION	COUNT	PERCENTAGE
Physician	133	7.4%
Pharmacist	176	9.8%
Other Health Professional	246	13.6%
Lawyer	3	0.2%
Consumer/Non Health Professional	1,243	69.0%

Data Source: VigiLyze (Dataset date: 07/04/2021, MedDRA version: 24.0)

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 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 preferrd term (PT)* related to the three COVID-19 vaccines in Lebanon, February 14, 2021 to April 30, 2021

Reported preferred terms* (MedDRA)	COUNT	PERCENTAGE
PT: Pain	796	44.5%
PT: Injection site pain	583	32.6%
PT: Chills	562	31.4%
PT: Fatigue	520	29.1%
PT: Headache	504	28.2%
PT: Pyrexia	381	21.3%
PT: Nausea	181	10.1%
PT: Injection site swelling	158	8.8%
PT: Injection site erythema	139	7.8%
PT: Abdominal pain	76	4.2%
PT: Diarrhoea	73	4.1%
PT: Dyspnoea	55	3.1%
PT: Myalgia	53	3.0%
PT: Cough	46	2.6%
PT: Vomiting	46	2.6%
PT: Rash	45	2.5%
PT: Tachycardia	41	2.3%
PT: Hypertension	37	2.1%
PT: Dizziness	36	2.0%
PT: Arthralgia	34	1.9%
PT: Respiratory symptom	33	1.8%
PT: Back pain	27	1.5%
PT: Oropharyngeal pain	27	1.5%
PT: Hypoaesthesia	24	1.3%
PT: Asthenia	22	1.2%
PT: Paraesthesia	18	1.0%
PT: Pain in extremity	16	0.9%
PT: Hypoaesthesia oral	16	0.9%
PT: SARS-CoV-2 test positive	14	0.8%
PT: Chest pain	13	0.7%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 three COVID-19 vaccines in Lebanon, February 14, 2021 to April 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	10	0.6%
SOC: Cardiac disorders	47	2.6%
SOC: Ear and labyrinth disorders	17	1.0%
SOC: Eye disorders	14	0.8%
SOC: Gastrointestinal disorders	306	17.1%
SOC: General disorders and administration site conditions	1,488	83.2%
SOC: Immune system disorders	7	0.4%
SOC: Infections and infestations	13	0.7%
SOC: Injury, poisoning and procedural complications	1	0.1%
SOC: Investigations	21	1.2%
SOC: Metabolism and nutrition disorders	5	0.3%
SOC: Musculoskeletal and connective tissue disorders	139	7.8%
SOC: Nervous system disorders	576	32.2%
SOC: Psychiatric disorders	6	0.3%
SOC: Renal and urinary disorders	2	0.1%
SOC: Reproductive system and breast disorders	5	0.3%
SOC: Respiratory, thoracic and mediastinal disorders	119	6.7%
SOC: Skin and subcutaneous tissue disorders	68	3.8%
SOC: Vascular disorders	52	2.9%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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)*

c.ii. Non-serious AEFIs

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

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Pain	605	44.8%
PR: Injection site pain	383	28.4%
PT: Chills	377	27.9%
PT: Headache	307	22.7%
PT: Fatigue	294	21.8%
PT: Pyrexia	244	18.1%
PT: Injection site swelling	122	9.0%
PT: Injection site erythema	115	8.5%
PR: Nausea	108	8.0%
PT: Diarrhoea	53	3.9%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 April 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	9	0.7%
SOC: Cardiac disorders	29	2.1%
SOC: Ear and labyrinth disorders	15	1.1%
SOC: Eye disorders	10	0.7%
SOC: Gastrointestinal disorders	206	15.3%
SOC: General disorders and administration site conditions	1,114	82.5%
SOC: Immune system disorders	4	0.3%
SOC: Infections and infestations	10	0.7%
SOC: Investigations	18	1.3%
SOC: Metabolism and nutrition disorders	3	0.2%
SOC: Musculoskeletal and connective tissue disorders	112	8.3%
SOC: Nervous system disorders	357	26.4%
SOC: Psychiatric disorders	4	0.3%
SOC: Renal and urinary disorders	2	0.1%
SOC: Reproductive system and breast disorders	2	0.1%
SOC: Respiratory, thoracic and mediastinal disorders	87	6.4%
SOC: Skin and subcutaneous tissue disorders	38	2.8%
SOC: Vascular disorders	18	1.3%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 8. Number and percentage of reported AEFIs (top 10) by symptom preferred term (PT)* related to AstraZeneca Vaccine in Lebanon, February 14, 2021 to April 30, 2021

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	163	59.1%
PT: Headache	150	54.3%
PR: Injection site pain	146	52.9%
PT: Pain	139	50.4%
PT: Chills	126	45.7%
PT: Pyrexia	103	37.3%
PR: Nausea	48	17.4%
PT: Injection site swelling	30	10.9%
PT: Injection site erythema	19	6.9%
PT: Abdominal pain	18	6.5%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 Vaccine in Lebanon, February 14, 2021 to April 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Cardiac disorders	2	0.7%
SOC: Eye disorders	4	1.4%
SOC: Gastrointestinal disorders	67	24.3%
SOC: General disorders and administration site conditions	260	94.2%
SOC: Immune system disorders	1	0.4%
SOC: Infections and infestations	1	0.4%
SOC: Musculoskeletal and connective tissue disorders	17	6.2%
SOC: Nervous system disorders	156	56.5%
SOC: Psychiatric disorders	1	0.4%
SOC: Reproductive system and breast disorders	1	0.4%
SOC: Respiratory, thoracic and mediastinal disorders	12	4.3%
SOC: Skin and subcutaneous tissue disorders	6	2.2%
SOC: Vascular disorders	3	1.1%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 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 April 30, 2021

Top Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	49	59.8%
PT: Chills	40	48.8%
PT: Pain	38	46.3%
PR: Injection site pain	36	43.9%
PT: Headache	35	42.7%
PT: Pyrexia	25	30.5%
PR: Nausea	14	17.1%
PT: Asthenia	6	7.3%
PT: Diarrhoea	5	6.1%
PT: Dizziness	4	4.9%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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, February 14, 2021 to April 30, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Gastrointestinal disorders	17	20.7%
SOC: General disorders and administration site conditions	76	92.7%
SOC: Infections and infestations	1	1.2%
SOC: Musculoskeletal and connective tissue disorders	5	6.1%
SOC: Nervous system disorders	38	46.3%
SOC: Reproductive system and breast disorders	1	1.2%
SOC: Respiratory, thoracic and mediastinal disorders	5	6.1%
SOC: Skin and subcutaneous tissue disorders	5	6.1%

Data Source: VigiLyze (Dataset date: 09/05/2021, 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 12. Number and percentage of reported follow-up AEFIs by symptom preferred term (PT)* related to Pfizer BioNTech Vaccine in Lebanon, February 14, 2021 to April 30, 2021

	Top 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	18	32.7%	52	3.8%	Recovered	Not Serious
	PT: Chills	15	27.3%				
	PT: Injection site pain	12	21.8%				
	PT: Rash	12	21.8%				
	PT: Fatigue	11	20.0%				
	PT: Pain	11	20.0%				
	PT: Tachycardia	11	20.0%				
	PT: Dyspnoea	8	14.5%				
	PT: Nausea	8	14.5%				
	PT: Headache	7	12.7%				
	PT: Pyrexia	5	9.1%				
	PT: Vomiting	5	9.1%				
	PT: Hypotension	4	7.3%				
	PT: Abdominal pain	3	5.5%				
	PT: Cough	3	5.5%				
	PT: Injection site rash	3	5.5%				
	PT: Urticaria	3	5.5%				
	PT: Chest discomfort	2	3.6%				
	PT: Dizziness	2	3.6%				
	PT: Hypoaesthesia	2	3.6%				
	PT: Injection site erythema	2	3.6%				
	PT: Laryngospasm	2	3.6%				
	PT: Respiratory symptom	2	3.6%				
	PT: Abdominal pain upper	1	1.8%				
	PT: Chest pain	1	1.8%				
	PT: Diarrhoea	1	1.8%				
	PT: Ecchymosis	1	1.8%				
	PT: Granuloma	1	1.8%				
Important Medical Events***	PT: Atypical pneumonia	1	1.8%	2			
	PT: Facial paralysis	1	1.8%				

Data Source: VigiLyze (Dataset date: 09/05/2021, 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.*
***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 (refer to technical notes).*

Table 13. Number and percentage of reported follow-up AEFIs by symptom preferred term (PT)* related to AstraZeneca Vaccine in Lebanon, February 14, 2021 to April 30, 2021

	Top 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	5	71.4%	7	2.5%	Recovered	Not Serious
	PT: Injection site pain	4	57.1%				
	PT: Chills	3	42.9%				
	PT: Fatigue	3	42.9%				
	PT: Nausea	3	42.9%				
	PT: Pyrexia	3	42.9%				
	PT: Injection site swelling	3	42.9%				
	PT: Abdominal pain	2	28.6%				
	PT: Hypertension	2	28.6%				
	PT: Myalgia	2	28.6%				
	PT: Pain	2	28.6%				
	PT: Paraesthesia	2	28.6%				
	PT: Tachycardia	2	28.6%				
	PT: Arthralgia	1	14.3%				
	PT: Axillary vein thrombosis	1	14.3%				
	PT: Bone pain	1	14.3%				
	PT: Diarrhoea	1	14.3%				
	PT: Ear pain	1	14.3%				
	PT: Feeling hot	1	14.3%				
	PT: Gingival pain	1	14.3%				
	PT: Hypersensitivity	1	14.3%				
	PT: Lymphadenopathy	1	14.3%				
	PT: Muscle spasms	1	14.3%				
	PT: Rash	1	14.3%				
	PT: Contusion	1	14.3%				
	PT: Respiratory symptom	1	14.3%				

Data Source: VigiLyze (Dataset date: 09/05/2021, 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.*
***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 (refer to technical notes).*

Table 14. Number and percentage of reported follow-up AEFIs by symptom preferred term (PT)* related to AstraZeneca Vaccine in Lebanon, February 14, 2021 to April 30, 2021

	Top 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: Hypotension	1	100.0%	1	2.5%	Recovered	Not Serious
	PT: Dyspnoea	1	100.0%				
Important Medical Events***	PT: Syncope	1	100.0%				

Data Source: VigiLyze (Dataset date: 09/05/2021, 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.*
***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 (refer to technical notes).*

DESCRIPTION OF ADVERSE EVENTS FOLLOWING IMMUNIZATION

The age group of vaccine recipients who mostly reported AEFIs was 18 to 44 years old (47.1%), with females reporting more AEFIs than males (65% vs. 35%) (Table 2).
The most reported AEFIs for all COVID-19 vaccines per symptom were general pain (44.5% of total reported AEFIs), injection site pain (32.6% of total reported AEFIs), and chills (31.4% of total reported AEFIs) (Table 4).

The most reported AEFIs by System Organ Class were general disorders and administration site conditions (83.2% of total reported AEFIs per SOC), followed by nervous system disorders (32.2% of total reported AEFIs per SOC), and gastrointestinal disorders (17.1% 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 (44.8% of total reported AEFIs related to Pfizer-BioNTech Vaccine) Fatigue was the most common adverse event following both AstraZeneca Vaccine (59% of total reported AEFIs related to AstraZeneca Vaccine) and Sputnik V Vaccine (59.8% of total reported AEFIs).

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 paragraph 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 those “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 (Tables 12, 13 and 14), the most reported AEFIs that required close monitoring were:

- Hypertension (18 case reports) for Pfizer BioNTech vaccine.
- Hypertension (2 case reports) for AstraZeneca vaccine.
- Axillary Vein Thrombosis (one case report) for AstraZeneca vaccine.
- Lymphadenopathy (one case report) for AstraZeneca vaccine.
- Contusion (one case report) for AstraZeneca vaccine.

Among the follow-up AEFIs (Tables 12, 13 and 14), the most reported important medical events were:

- Atypical pneumonia and facial paralysis (one case report each) for Pfizer BioNTech Vaccine.
- Syncope (1 case report) for Sputnik V Vaccine

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

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 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°603/1.

In the period of time covered by this report, there were 31 case reports classified as serious, representing 1.7% of all case reports and a serious AEFI reporting rate of 0.07 per 1,000 doses of vaccines. Twenty four recipients were above 75 years old, 4 were between 45 and 64 years old and 3 were between 18 and 44 years old. The 31 vaccine recipients experienced AEFIs within 20 minutes to 33 days after being vaccinated. Out of the 31 vaccine recipients, 12 died and 19 were hospitalized.

Update on the 11 serious cases' investigation discussed in the Report #1:

The 6 hospitalized cases are presented below:

- Three case reports related to the SOC "Nervous System Disorder" were cerebrovascular accidents (CVAs). The vaccine recipients have multiple co-morbidities and concomitant medications. Two cases of CVAs occurred 5 and 12 days following the first dose of Pfizer BioNTech Vaccine and the third case occurred 1 day following the second dose of Pfizer BioNTech Vaccine.

- One case report related to the SOC "Immune System Disorder" was a severe allergy. The vaccine recipient has no co-morbidities nor concomitant medications. The allergy occurred 15 days following the first dose of Pfizer BioNTech Vaccine.

- One case report related to the SOC "Immune System Disorder" was a hyper stimulation of immune system. The vaccine recipient has Hashimoto disease. The hyper stimulation of immune system occurred 1 day following the second dose Pfizer BioNTech Vaccine. It is also worth mentioning that the recipient was tested positive for COVID-19 prior to receipt of the second dose of Pfizer BioNTech Vaccine.

- One case report related to the SOC "Investigation" was a decrease in oxygen saturation. The vaccine recipient has a chronic obstructive pulmonary disease. The desaturation occurred 7 days following the second dose of Pfizer BioNTech Vaccine.

- The six hospitalized cases were discharged. The investigation and causality assessment are completed. The investigation of the causal relationship with the vaccine is ongoing by the Serious AEFI Special Committee at MoPH.

- Five cases resulted in death 24 hours to 5 days following receipt of Pfizer BioNTech Vaccine. The vaccine recipients were above 75 years old with significant co-morbidities. The investigation and causality assessment have been finalized. The results are being reviewed by the Serious AEFI Special Committee at MoPH.

New serious cases

The 19 hospitalized cases are presented below:

- Eight case reports following Pfizer BioNTech Vaccine did not require further investigation and were being followed-up over the phone. Out of which; six cases recovered and were discharged from the hospital. These include: SARS-COV-2 test positive (1 case report), Dyspnea (1 case report), Syncope (1 case report), Hypotension and Bradycardia (1 case report), Hypertension (1 case report), and Urticaria (1 case report). While the remaining two cases that included one case of Vomiting (recovering) and a case of Tachycardia associated with vomiting (did not recover yet) are still under ongoing follow up.

- Four case reports related to the SOC "Nervous System Disorder" were ischemic CVAs. The vaccine recipients have multiple co-morbidities and concomitant medications. The cases of CVAs occurred 7, 8 and 19 days following the first dose of Pfizer BioNTech Vaccine and the fourth case occurred the same day following the second dose of Pfizer BioNTech Vaccine. The four cases are recovering. The investigation and causality assessment have been finalized; the results will be reviewed by the Serious AEFI Special Committee at MoPH.

- One case related to the SOC "Vascular Disorder" was Peripheral vascular disease (thrombosis of left axillary artery). The vaccine recipient has significant co-morbidities and concomitant medications. The case occurred 5 days following the first dose of Pfizer BioNTech Vaccine. The case is recovering. The investigation and causality assessment have been finalized; the results will be reviewed by the Serious AEFI Special Committee at MoPH.

Seven cases resulted in death 24 hours to 16 days following the receipt of Pfizer BioNTech Vaccine. Four vaccine recipients experienced death as a result of ischemic CVA, 2 cases following sudden cardiac arrest and 1 as a result of myocardial infarction. The vaccine recipients were above 80 years old except for one patient who was 58 years old, all with significant co-morbidities. The investigation and causality assessment have been finalized; the results will be reviewed by the Serious AEFI Special Committee at MoPH.

COMPARISON WITH INTERNATIONAL AEFI DATA

The most frequently reported AEFIs in the global database (Vigibase) in regard to the three COVID-19 vaccine described in this report were headache (39.4% of total reported AEFIs), pyrexia (31.9% of total reported AEFIs), chills (23.2% of total reported AEFIs), fatigue (23.0% of total reported AEFIs), and myalgia (17.6% of total reported AEFIs). The results are compatible with the national data which include headache, chills, and fatigue in the 5 most reported AEFIs in Lebanon (Table 4).

In regards to serious AEFIs by Pfizer BioNTech Vaccine, Hypertension was declared a signal (refer to technical notes) in France, according to The National Agency for the Safety of Medicines and Health Products (ANSM). As more than 30 case reports in Lebanon included hypertension, this AEFI is currently under surveillance. Arrhythmia following Pfizer BioNtech Vaccine was also declared as a potential signal according to the ANSM. Cases in which related AEFI has been identified are currently under surveillance as well by the PV team.

CONCLUSION

In the scope of the post-marketing surveillance conducted by the PV Program, a total of 1,801 case reports/ 4,896 AEFIs were received and analyzed following a total of 462,722 doses of COVID-19 vaccines (Pfizer BioNTech Vaccine, COVID-19 Vaccine AstraZeneca Vaccine, Sputnik V Vaccine) administered in Lebanon from February 14th till 30th April 2021. This is equivalent to a reporting rate of 3.9 case reports/10.6 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.
Hypertension and CVAs following vaccination with Pfizer BioNTech Vaccine are potential signals.

The PV Program continues to conduct continuous monitoring of 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) 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.
- MedDRA (Medical Dictionary tor Regulatory Activities) is a standardised medical terminology, published by the International Council for Harmonisation, 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 Programme 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.
- VigiFlow is a web-based individual case safety report (ICSR) management system that is available for use by national PV centres 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 programme. 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 have been excluded.
- In the period of time covered by the report, case reports related to Sputnik V Vaccine were of a small amount.
- 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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