Adverse Events Following Medications and Vaccines Use in Lebanon

National Pharmacovigilance Report

Reporting Period:

November 1st, 2024 – November 30th,2025

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GLOSSARY OF TERMS[1]

Adverse Drug Reaction (ADR)

A response to a medicinal product which is noxious and unintended.

Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

Adverse Event (AE)

Any untoward medical occurrence in a patient or a clinical trial subject administered a medicinal product does not necessarily have a causal relationship with this.

An adverse event can therefore be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with using a medicinal product, whether or not related to the medicinal product.

Adverse Event Following Immunization (AEFI)

Any untoward medical occurrence following immunization which does not necessarily have a causal relationship to the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Individual Case Safety Report (ICSR); synonym: Adverse (drug) Reaction Report

Format and content for the reporting of one or several suspected adverse reactions to a medicinal product that occur in a single patient at a specific point of time.

International Council for Harmonization (ICH)

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines.

Marketing Authorization Holder (MAH)

The company or other legal entity that has the authorization to market a medicine.

Medical Dictionary for Regulatory Activities (MedDRA)

A rich and highly specific standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans.

Pharmacovigilance (PV)

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[1] *World Health Organization (WHO) pharmacovigilance definitions*
International Council for Harmonization (ICH) Guidelines (e.g. ICH E2A, E2D)
Good Pharmacovigilance Practices (GVP) Modules
EU Directive 2001/83/EC (as applicable)

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

Preferred Term (PT)

A preferred term (PT) is the description that is deemed to be the most clinically appropriate way of expressing a concept in a clinical record. It represents a common word or phrase used by clinicians to name a concept in clinical practice or in the literature.

System Organ Class (SOC)

System Organ Classes (SOCs) which are groupings by etiology (e.g. Infections and infestations), manifestation site (e.g. Gastrointestinal disorders) or purpose (e.g. Surgical and medical procedures).

WHO Program for International Drug Monitoring (PIDM)

The WHO Program for International Drug Monitoring (WHO PIDM) is an international collaboration with the goal to ensure identification of medicines and vaccine-related safety problems.

EXECUTIVE SUMMARY

This executive summary provides an overview of reported Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs) that were temporally associated (i.e., occurred after administration of the drug/vaccine) with medications and vaccines available in Lebanon between November 1st, 2024, and November 30th, 2025.

Total Number of emails Received From MAHs	Total Number of Initial ICSRs Received From MAHs	Total Number of Initial ICSRs Received From e-Reporting e-Form
1,586 emails	820 (92.3%)	93 (12.7%)

BACKGROUND

In Lebanon, the Lebanese National Pharmacovigilance Program (LNPVP), instituted under the Ministry of Public Health's (MoPH) Quality Assurance of Pharmaceutical Products Program (QAPPP), gained full membership to the WHO Program for International Drug Monitoring (PIDM) in 2021 (1). With this membership, the LNPVP became the officially recognized National Competent Authority for pharmacovigilance and in Lebanon.

To strengthen pharmacovigilance, regulations were introduced, requiring Market Authorization Holders (MAHs) to report Adverse Drug Reactions (ADRs) in compliance with the International Council for Harmonization (ICH) E2B (R2) and (R3) electronic standards (2,3). These regulations were reinforced through Ministerial Resolutions #180 and #181 issued in 2021 requesting MAHs to submit retrospective ADR data for periods prior to 2018 (4), in addition to ensuring continuous reporting of ADR data from 2018 onwards in accordance with the applicable regulations. All ADR data, both retrospective and ongoing, managed by the LNPVP using VigiFlow "a WHO web-based system for ADR case management" was then uploaded to VigiBase, the global ADR database, contributing to the international pharmacovigilance landscape (5).

Recognizing the importance of comprehensive data collection, the LNPVP has also implemented various reporting tools for other stakeholders, including patients and healthcare professionals. These tools include an e-reporting platform, the Med Safety App, and the VigiMobile e-Reporting e-Form applications for medicines and vaccines (6). The aim is to encourage accessible and diverse channels for reporting ADRs, thereby enhancing the scope of pharmacovigilance data and supporting public health efforts (6).

All ADR reports are directly integrated into VigiFlow. Reports collected from various sources undergo screening to ensure data completion and accuracy, with any incomplete or inconsistent reports subject to follow-up by the LNPVP. Each case report is also evaluated through causality assessment, an essential process for determining the likelihood that a particular drug or vaccine was the cause of the reported reaction (7). Through these stringent procedures, the LNPVP maintains high standards of data quality, supporting its mission to identify, assess, and prevent drug-related risks, thereby safeguarding public health.

A. REPORTING OVERVIEW

1. Summary of Received Data

During the reporting period (November 1st, 2024 – November 30th, 2025), the Lebanese National Pharmacovigilance Program (LNPVP) received **1,586 emails** from approximately **30 pharmaceutical companies**, containing **1,838 XML files**. These resulted in **820** valid initial Individual Case Safety Reports **(ICSRs)** submitted by Marketing Authorization Holders (MAHs). In addition, 93 valid case reports were received through other reporting channels, including healthcare professionals and patients. After data validation and exclusion of follow-up reports, technically invalid cases, and cases occurring outside Lebanon (42 case reports), a total of 920 initial case reports were included in the analysis, comprising 877 medication-related reports and 43 vaccine-related reports. **(Table 1)**

A total of 387 reports did not include a suspected adverse drug reaction and were therefore classified as adverse events with no suspected ADR. These reports were retained for descriptive analysis and are presented in a dedicated section of this report **"Adverse Events with no Suspected Drug Reactions".**

Table 1. *Summary of all case reports received by XML or by Other Means of Reporting, related to* ***medications*** *and* ***vaccines****, available in Lebanon, between November 1st, 2024, and November 30th, 2025.*

Month / Year	Emails	ICSRs	MAH Cases	Other Means	Total Cases	ADRs	AEFIs	No Reaction	Failed To be Imported	Follow up Reports	Outside Lebanon	Number of Companies
November 2024	91	90	35	1	36	32	4	18	5	31	1	20
December 2024	86	101	38	7	45	43	2	23	4	26	0	23
January 2025	120	136	39	7	45	43	2	41	3	53	0	25
February 2025	95	98	37	8	46	46	0	18	8	35	0	23
March 2025	124	148	79	15	97	94	3	9	1	41	18	23
April 2025	204	230	96	0	96	96	0	91	3	51	2	23
May 2025	131	157	86	11	98	88	10	14	1	64	7	21
June 2025	156	178	52	6	58	58	0	71	2	48	6	25
July 2025	127	129	60	11	72	72	0	19	2	50	0	23
August 2025	86	102	51	4	55	49	6	12	2	36	0	19
September 2025	121	149	64	6	70	64	6	33	3	47	2	22
October 2025	108	139	63	11	74	68	6	22	1	49	4	30
November 2025	137	181	120	8	128	124	4	16	2	41	2	27
Total	**1,586**	**1,838**	**820**	**93**	**920**	**877**	**43**	**387**	**37**	**572**	**42**	**Mean = 24**

2. Demographics

Table 2. *Summary of all case reports by age group and gender related to the* ***medications*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Gender	N (%)
Female	432 (49.2)
Male	337 (38.4)
Unknown	108 (12.4)
Age Group	**N (%)**
≥ 75 years	73 (8.4)
65 - 74 years	91 (10.4)
45 - 64 years	219 (24.9)
18 - 44 years	154 (17.5)
12- 17 years	44 (5.1)
1 - 11 years	31 (3.5)
Unknown	265 (30.2)
Total	**877 (100)**

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1)

Note: Age represents the age at time of medication/vaccine intake. Some case reports may be missing the date of birth

ADR case reports were mostly received from females (49.2%) and from individuals aged 45-64 years-old (24.9%). The relatively high proportion of reports with unknown age reflects incomplete demographic information in spontaneous reports, particularly those submitted retrospectively or by non-healthcare professionals.

Table 3*. Summary of all case reports by age group and gender related to the* ***vaccines*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Gender	N (%)
Female	11 (25.6)
Male	19 (44.2)
Unknown	13 (30.2)
Age Group	**N (%)**
≥ 75 years	1 (2.3)
65 - 74 years	4 (9.3)
45 - 64 years	5 (11.6)
18 - 44 years	4 (9.3)
12- 17 years	0
1 - 11 years	10 (23.3)
Unknown	19 (44.2)
Total	43 (100)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1)

Note: Age represents the age at time of medication/vaccine intake. Some case reports may be missing the date of birth

AEFI case reports were received mostly from males (44.2%), and from individuals aged 1-11 years-old (23.3%).

3. Reporter Qualification

Table 4. *Summary of all case reports by reporter qualification related to the* ***medications*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Reporter Qualification	N (%)
Physician	427 (48.7)
Consumer or other non-health professional	356 (40.6)
Other health professionals	196 (21.5)
Pharmacist	54 (6.2)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might include more than one reporter and reporter qualification

ADR case reports were mostly received from physicians (48.7%) followed by consumers (40.6%). Percentages may exceed 100% as a single case report can include more than one reporter or reporter qualification.

Table 5. *Summary of all case reports by reporter qualification related to the* ***vaccines*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Reporter Qualification	N (%)
Physician	22 (51.1)
Consumer or other non-health professional	14 (32.6)
Other health professional	7 (16.3)
Pharmacist	4 (9.3)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might include more than one reporter and reporter qualification

AEFI case reports were mostly received from physicians (51.1%) followed by consumers (32.6%). Percentages may exceed 100% as a single case report can include more than one reporter or reporter qualification.

4. Overview of Adverse Events (ADRs and AEFIs)

Table 6. *Summary of number and percentage of Top 20 ADRs by reported Preferred Terms (PTs) related to the* ***medications*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Drug Reaction (PT*)	Number (%)
Off label use	99 (11.3)
Cytopenia	75 (8.6)
Disease progression	53 (6.0)
Nausea	36 (4.1)
Rash	32 (3.6)
Drug ineffective	29 (3.3)

Adverse Drug Reaction (PT*)	Number (%)
Malignant neoplasm progression	28 (3.2)
Fatigue	26 (3.0)
Death	25 (2.9)
Pruritus	24 (2.7)
Vomiting	24 (2.7)
Chills	23 (2.6)
Headache	22 (2.5)
Pyrexia	19 (2.2)
Diarrhea	19 (2.2)
Dyspnea	17 (1.9)
Hypersensitivity	17 (1.9)
Product use in unapproved indication	16 (1.8)
Inappropriate schedule of product administration	15 (1.7)
Erythema	14 (1.6)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might contain more than one reaction.
**PT: Preferred Term*

The most frequently reported Preferred Terms included medication-use–related terms were: off-label use (11.3%) as well as clinical adverse reactions such as cytopenia (8.6%) and disease progression (6.0%).

Table 7. *Summary of number and percentage of reported ADRs by System Organ Class (SOC) related to the* ***medications*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Drug Reaction (SOC*)	N (%)
General disorders and administration site conditions	257 (29.3)
Injury, poisoning and procedural complications	188 (21.4)
Gastrointestinal disorders	115 (13.1)
Blood and lymphatic system disorders	102 (11.6)
Skin and subcutaneous tissue disorders	101 (11.5)
Nervous system disorders	89 (10.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	74 (8.4)
Infections and infestations	69 (7.9)
Investigations	65 (7.4)
Respiratory, thoracic and mediastinal disorders	62 (7.1)
Musculoskeletal and connective tissue disorders	48 (5.5)
Vascular disorders	36 (4.1)
Metabolism and nutrition disorders	32 (3.6)

Adverse Drug Reaction (SOC*)	N (%)
Immune system disorders	30 (3.4)
Cardiac disorders	28 (3.2)
Psychiatric disorders	22 (2.5)

*Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1). *SOC: System Organ Class*
Note: A single case report might contain more than one reaction. A single reaction can be classified in multiple SOC.

The most frequently reported adverse drug reactions were related to **general symptoms and administration site reactions**, classified under General disorders and administration site conditions (29.3%). These reactions mainly include non-specific systemic symptoms such as fever, fatigue, pain, and malaise, as well as reactions occurring at the site of administration, including injection-site pain, swelling, or redness.

This was followed by adverse events classified under Injury, poisoning and procedural complications (21.4%), which encompass events associated with medication errors, incorrect administration, accidental exposure, overdoses, and complications related to medical procedures. These findings highlight that a substantial proportion of reported adverse events were related not only to the pharmacological effects of medicines and vaccines, but also to their handling, administration, and use in clinical practice.

Table 8. *Summary of number and percentage of reported ADRs Preferred Term (PT) per System Organ Class (SOC) related to the* ***medications*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Drug Reaction (PT*) Per (SOC**)	N (%)
General disorders and administration site conditions	**257(29.3)**
Disease progression	53 (6.0)
Drug ineffective	29 (3.3)
Fatigue	26 (3.0)
Injury, poisoning, and procedural complications	**188 (21.4)**
Off label use	99 (11.3)
Product use in unapproved indication	16 (1.8)
Inappropriate schedule of product administration	15 (1.7)
Gastrointestinal disorders	**115 (13.1)**
Nausea	36 (4.1)
Vomiting	24 (2.7)
Diarrhea	19 (2.2)
Blood and lymphatic system disorders	**102 (11.6)**
Cytopenia	75 (8.6)
Anemia	5 (0.5)
Thrombocytopenia	7 (0.7)
Skin and subcutaneous tissue disorders	**101 (11.5)**
Erythema	14 (1.6)
Rash	32 (3.6)
Pruritus	24 (2.7)

*Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1). *PT: Preferred Term. **SOC: System Organ Class*
Note: A single case report might contain more than one reaction. A single reaction can be classified in multiple SOC

Out of 870 reported adverse drug reactions (ADRs), the most frequently reported System Organ Class was General disorders and administration site conditions (29.3%), followed by Injury, poisoning, and procedural complications (21.4%). A notable proportion of reports related to medication use issues, particularly off-label use (11.3%). Gastrointestinal disorders (13.1%), blood and lymphatic system disorders (11.6%), and skin and subcutaneous tissue disorders (11.5%) were also commonly reported, with cytopenia (8.6%) representing the most frequent hematological reaction.

***Table 9**. Summary of number and percentage of Top 20 AEFIs reported per Preferred Terms (PTs) related to the **vaccines** available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Event Following Immunization (PT*)	**N** (%)
Vaccination site erythema	16 (37.2)
Vaccination site swelling	15 (34.8)
Pyrexia	8 (18.6)
Fatigue	6 (13.9)
Vaccination site pain	5 (11.6)
Erythema	4 (9.3)
Pain	4 (9.3)
Blood glucose decreased	2 (4.6)
Chest pain	2 (4.6)
Depression	2 (4.6)
Rhinorrhea	2 (4.6)
Swelling	2 (4.6)
Vomiting	2 (4.6)
Vaccination site induration	2 (4.6)
Accidental underdose	2 (4.6)
Loss of personal independence in daily activities	2 (4.6)
Amyotrophic lateral sclerosis	1 (2.3)
Application site erythema	1 (2.3)
Arthropathy	1 (2.3)
Asthenia	1 (2.3)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might contain more than one reaction.
**PT: Preferred Term*

The top 3 reported AEFIs/PTs were: Vaccination site erythema (37.2), Vaccination site swelling (34.8), and Pyrexia (18.6).

Table 10. Summary of number and percentage of reported AEFIs by System Organ Class (SOC) related to the vaccines available in Lebanon, between November 1st, 2024, and November 30th, 2025

Adverse Event Following Immunization (SOC*)	**N (%)**
General disorders and administration site conditions	32 (74.4)
Nervous system disorders	6 (13.9)
Skin and subcutaneous tissue disorders	6 (13.9)

Adverse Event Following Immunization (SOC*)	N (%)
Injury, poisoning and procedural complications	4 (9.3)
Gastrointestinal disorders	3 (6.9)
Investigations	3 (6.9)
Musculoskeletal and connective tissue disorders	3 (6.9)
Psychiatric disorders	3 (6.9)
Respiratory, thoracic, and mediastinal disorders	3 (6.9)
Social circumstances	2 (4.6)
Blood and lymphatic system disorders	1 (2.3)
Eye disorders	1 (2.3)
Immune system disorders	1 (2.3)
Infections and infestations	1 (2.3)
Renal and urinary disorders	1 (2.3)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might contain more than one reaction. A single reaction can be classified in multiple SOC
**SOC: System Organ Class*

Among the reported adverse events following immunization, General disorders and administration site conditions were the most frequently reported System Organ Class, accounting for **74.4%** of reports, mainly reflecting vaccination site reactions such as injection-site erythema, injection-site swelling, and pyrexia.

This was followed by Nervous system disorders and Skin and subcutaneous tissue disorders, each representing **13.9%** of the reported adverse events, including symptoms such as headache, head discomfort, lethargy, erythema, and allergic skin reactions.

***Table 11**. Summary of number and percentage of reported AEFIs by Preferred Term (PT) per System Organ Class (SOC) related to the **vaccines** available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Events Following Immunization (PT*) Per (SOC**)	N (%)
General disorders and administration site conditions	**32 (74.4)**
Vaccination site erythema	16 (37.2)
Vaccination site swelling	15 (34.8)
Pyrexia	8 (18.6)
Nervous system disorders	**6 (13.9)**
Head discomfort	1 (2.3)
Headache	1 (2.3)
Lethargy	1 (2.3)
Skin and subcutaneous tissue disorders	**6 (13.9)**
Erythema	4 (9.3)
Dermatitis allergic	1 (2.3)
Skin ulcer	1 (2.3)

Data Source: VigiLyze (Dataset date: 25/12/2025, MedDRA version: 28.1).
Note: A single case report might contain more than one reaction. A single reaction can be classified in multiple SOC
**PT: Preferred Term. **SOC: System Organ Class*

A total of 43 adverse events following immunization (AEFIs) were reported and classified by System Organ Class (SOC) and Preferred Term (PT) according to MedDRA terminology. The majority of reports were categorized under General disorders and administration site conditions, accounting for 32 reports (74.4%). Within this SOC, the most frequently reported PTs were vaccination site erythema in 16 cases (37.2%) and vaccination site swelling in 15 cases (34.8%), followed by pyrexia reported in 8 cases (18.6%). Nervous system disorders were reported in 6 cases (13.9%), with individual reports of head discomfort, headache, and lethargy, each accounting for 1 report (2.3%).

Similarly, skin and subcutaneous tissue disorders accounted for 6 reports (13.9%), predominantly erythema in 4 cases (9.3%), while allergic dermatitis and skin ulcer were each reported once (2.3%). Overall, the reported AEFIs were mainly mild local and systemic reactions, consistent with expected post-vaccination reactogenicity profiles.

5. Seriousness Criteria of Received Adverse Events

Table 12. *Description of seriousness and seriousness criteria of the case reports related to the medications available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Seriousness	**N (%)**
Non-Serious	493 (56.2)
Serious	384 (43.7)
Seriousness Criteria	
Caused / prolonged hospitalization	204 (53.1)
Congenital anomaly	3 (0.8)
Disabling/incapacitating	5 (1.3)
Life Threatening	14 (3.6)
Other medically important	254 (66.1)
Results in death	51 (13.3)

Non-serious ADRs (56.2%) were more frequently reported than serious ones (43.7%). Among serious cases, the most common seriousness criterion was “other medically important conditions” (66.1%), followed by caused or prolonged hospitalization (53.1%). Other medically important conditions refer to events that may not be immediately life-threatening or result in hospitalization but are considered clinically significant and may require medical intervention to prevent serious outcomes.

A single serious case may fulfill more than one seriousness criterion; therefore, percentages are not mutually exclusive and may exceed 100%.

Table 13*. Description of seriousness and seriousness criteria of the case reports related to the* ***vaccines*** *available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Seriousness	**N (%)**
Non-Serious	35 (81.4)
Serious	8 (18.6)
Seriousness Criteria	

Seriousness	N (%)
Caused / prolonged hospitalization	4 (50.0)
Disabling/incapacitating	1 (25.0)
Life Threatening	0
Other medically important	4 (50.0)
Results in death	1 (25.0)

Non-serious AEFIs (81.4%) were dominant compared to serious cases (18.6%). Among serious AEFIs, **"other medically important conditions"** and **"caused or prolonged hospitalization"** were the most frequently reported seriousness criteria (each 50.0%). Other medically important conditions include adverse events that, although not classified as life-threatening or resulting in death, are deemed medically significant and warrant clinical attention.

A single serious case may fulfill more than one seriousness criterion; therefore, percentages are not mutually exclusive and may exceed 100%.

B. ADVERSE EVENTS WITH NO SUSPECTED DRUG REACTION

From November 2024 to November 2025, 387 cases were received from the MAH and Other means of reporting and were classified as Adverse Events with No Reactions. Below is a summary of the description of these cases:

1. ATC Classification of Medications with No Suspected Drug Reactions

***Table 14**. Summary of the number and percentage of the reported Anatomical Therapeutic Chemical (ATC) codes, related to the **medications** available in Lebanon, between November 1st, 2024, and November 30th, 2025*

ATC Class	N* (%)
Antineoplastic and Immunomodulating Agents	330 (85.3)
Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins	89 (22.9)
Alimentary Tract and Metabolism	85 (21.9)
Nervous System	29 (7.4)
Musculo-Skeletal System	28 (7.2)
Anti-infective for Systemic Use	19 (4.9)
Blood And Blood Forming Organs	11 (2.8)
Dermatological	11 (2.8)
Respiratory System	9 (2.3)
Cardiovascular System	8 (2.1)
Genito Urinary System and Sex Hormones	6 (1.5)
Various	2 (0.5)

*Data Source: VigiLyze (Dataset date: **25/12/2025**, MedDRA version: 28.1).*
*Note: A single case report might contain more than one reaction. *A single case can contain multiple suspected drug products*

The most frequently reported ATC drug class among medications associated with adverse events that did not result in an adverse drug reaction was antineoplastic and immunomodulating agents (85.4%).

2. Overview of Adverse Events with No Suspected Drug Reactions

***Table 15.** Summary of number and percentage of reported Adverse Events with No Reactions by Preferred Term (PT) per System Organ Class (SOC) related to the **medications** available in Lebanon, between November 1st, 2024, and November 30th, 2025*

Adverse Event (PT*) Per (SOC**)	N (%)
Injury, poisoning, and procedural complications	**387 (100)**
Off-label use	259 (66.9)
Product dose omission issue	32 (8.2)
General disorders and administration site conditions	**181 (46.7)**
Drug ineffective	50 (12.9)
No adverse event	105 (27.1)
Product issues	**48 (12.4)**
Device malfunction	5 (1.2)
Product container issue	3 (0.7)

*Data Source: VigiLyze (Dataset date: **25/12/2025**, MedDRA version: 28.1). Note: A single case report might contain more than one reaction. A single reaction can be classified in multiple SOC. *PT: Preferred Term. **SOC: System Organ Class*

A total of 387 reports (100%) were classified under the System Organ Class (SOC) Injury, poisoning, and procedural complications. Within this SOC, the most frequently reported Preferred Term (PT) was off-label use, accounting for 259 reports (66.9%), followed by product dose omission issues reported in 32 cases (8.2%).

The SOC General disorders and administration site conditions were reported in 181 cases (46.7%). Among these, drug ineffective was identified in 50 reports (12.9%), while 105 reports (27.1%) explicitly indicated no adverse event, reflecting cases primarily related to medication use issues rather than clinical safety outcomes.

Additionally, Product issues were reported in 48 cases (12.4%), with device malfunction noted in 5 reports (1.2%) and product container issues in 3 reports (0.7%). Overall, the findings demonstrate that the majority of reports were related to medication use, handling, or effectiveness concerns, rather than documented adverse drug reactions.

To note, a single report may be coded under more than one System Organ Class (SOC) according to MedDRA rules; therefore, SOC categories presented below are not mutually exclusive.

It should be noted that **a single case may be classified under more than one System Organ Class**, which explains the presence of additional SOCs such *as* General disorders and administration site conditions *in* the table. The distribution across SOCs, therefore, reflects the coding structure of MedDRA rather than mutually exclusive categories.

C. SIGNAL DETECTION AND REPORTING

Signal detection, assessment, and reporting are fundamental in pharmacovigilance, as they help identify new risks associated with medicinal products and ensure public health safety. This process relies heavily on case reports, which are submitted by healthcare professionals, patients, and pharmaceutical companies. These reports contain important details about Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs), including patient demographics, drug exposure, clinical outcomes, and any suspected causal relationships. Once collected, the reports are analyzed using various signal detection methodologies, such as disproportionality analysis in pharmacovigilance databases, pattern recognition, and clinical case review. A signal is considered valid if there is sufficient evidence suggesting a potential new risk or a change in the known safety profile of a drug. The Good Pharmacovigilance Practices (GVP) Module IX – Signal Management is the guideline related to signal detection in pharmacovigilance. It provides a structured framework for identifying, assessing, and managing signals of potential safety concerns related to medicinal products (8).

The Lebanese National Pharmacovigilance Program (LNPVP) plays a key role in assessing these signals by reviewing case reports alongside epidemiological data, literature reviews, and preclinical findings to confirm their relevance.

Marketing Authorization Holders (MAHs) are responsible for continuously monitoring their products' safety and promptly reporting any emerging signals to the LNPVP. During the reporting period from

November 2024 to November 2025, MAHs identified and submitted safety signals to the LNPVP in accordance with established pharmacovigilance requirements. These signals have been provided in both hard copy format and as soft copies via emails (pv.moph@gmail.com and pv@moph.gov.lb), ensuring proper documentation and regulatory compliance. Despite contextual challenges related to the country's situation, signal detection and reporting activities continued throughout the reporting period.

The table below describes the signals received during the reporting period from November 2024 to November 2025. During this period, the LNPVP received a total of 31 safety signals related to registered medicinal products in Lebanon. The signals described in this section were identified through international regulatory authorities and routine regulatory intelligence activities.

These signals do not necessarily originate from case reports submitted within Lebanon but are monitored by the LNPVP as part of its signal tracking and regulatory oversight responsibilities.

Table 16. *Description of the Signals received between November 1st, 2024, and November 30th, 2025*

Medication	Signal Description	Source	Link	Date
Azilsartan	Intestinal angioedema	Authority website-EMA-PRAC	https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-28-31-october-2024-prac-meeting_en.pdf	Dec-24
Azilsartan & Chlortalidone	Intestinal angioedema	Authority website-EMA-PRAC	https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-28-31-october-2024-prac-meeting_en.pdf	Dec-24
Pemetrexed	Drug-drug interaction between proton pump inhibitors and Pemetrexed	Authority website-EMA-PRAC	https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-30-september-03-october-2024_en.pdf	Dec-24
Infliximab	Post-procedural complication (including infectious and non-infectious complications)	Authority website- TGA	Product Information safety updates - November 2024 | Therapeutic Goods Administration (TGA)	Dec-24
Infliximab	Paradoxical drug-induced immune disorders (e.g., new onset psoriasis)	Authority website- TGA	Product Information safety updates - November 2024 | Therapeutic Goods Administration (TGA)	Dec-24
Infliximab	Restricting administration at the discretion of the treating physician if the patient has a planned surgical procedure	Authority website- TGA	Product Information safety updates - November 2024 | Therapeutic Goods Administration (TGA)	Dec-24
Budesonide & Formoterol	Hypokalemia	Authority Websites - aemps	https://www.aemps.gob.es/informa/boletin-sobre-seguridad-de-medicamentos-de-uso-humano-julio-y-agosto-de-2024/	Dec-24
Naproxen	Fixed drug eruption	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Dec-24
Naproxen	Generalized bullous fixed drug eruption	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Dec-24
Candesartan	Intestinal angioedema	Authority website-EMA-PRAC	https://www.ema.europa.eu/en/documents/prac-	Dec-24

Medication	Signal Description	Source	Link	Date
Diclofenac	Fixed drug eruption	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Dec-24
Diclofenac	Generalized bullous fixed drug eruption	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Dec-24
Azacitidine	Cutaneous vasculitis	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Jan-25
Palbociclib	Venous thromboembolism	Authority website-X	Drug Safety-related Labeling Changes	Jan-25
Cefazolin	A fall in prothrombin Activity	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Jan-25
Cefazolin	False postiive reaction for glucose in the urine	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Jan-25
Cefazolin	Clostridioides difficile	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Jan-25
Gemcitabine	Oculomucocutaneo us syndrome	Authority website-PMDA	https://www.pmda.go.jp/files/000272712.pdf	Jan-25
Gemcitabine	Stevens-Johnson-Syndrome	Authority website-PMDA	https://www.pmda.go.jp/files/000272712.pdf	Jan-25
Letrozole	Musculoskeletal and connective tissue disorders	Authority website-FDA-SRLCs	Drug Safety-related Labeling Changes (SrLC)	Jan-25
Esomeprazole	Drug reaction with eosinophilia and systemic symptoms (DRESS)	Authority webiste-aemps	https://www.aemps.gob.es/informa/boletin-sobre-seguridad-de-	Jan-25
Gemcitabine	Toxic epidermal necrolysis	Authority website-PMDA	https://www.pmda.go.jp/files/000272712.pdf	Jan-25
Alogliptin & Metformin	Aggravation of MELAS syndrome/MIDD due to the risk of lactic acidosis exacerbation and neurologic complications with metformin in patients with known mitochondrial diseases	Authority website- EMA-PSUSA	Metformin: CMDh scientific conclusions and grounds for the variation, amendments to the product information and timetable for the implementation - PSUSA/00002001/202404	Feb-25
Azilsartan	Intestinal Angioedema	Authority website- EMA-PSUSA	https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-28-31-october-2024-prac-meeting_en.pdf	Feb-25

Medication	Signal Description	Source	Link	Date
Azilsartan and Chlortalidone	Intestinal Angioedema	Authority website- EMA-PSUSA	https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-28-31-october-2024-prac-meeting_en.pdf	Feb-25
Palbociclib	Blood creatinine increased	Authority website-TGA	https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2017-PI-01659-1	Mar-25
Pioglitazone & Metformin	Aggravation of MELAS syndrome/MIDD due to the risk of lactic acidosis exacerbation and neurologic complications with metformin in patients with known mitochondrial diseases	Authority website-EMA-PSUSA	Metformin: CMDh scientific conclusions and grounds for the variation, amendments to the product information and timetable for the implementation - PSUSA/00002001/202404	Mar-25
Midazolam	Risk of miscarriage	Authority website - Medsafe	https://www.medsafe.govt.nz/profs/adverse/Minutes199.htm	Mar-25
Rosuvastatin	Myasthenia gravis, including ocular myasthenia	Authority website - Health Canada	http://canada.ca/	Mar-25
Piperacillin & Tazobactam	Rhabdomyolysis	Authority website - FDA - SRLCs	Drug Safety-related Labeling Changes (SrLC)	Mar-25
VARILRIX	Encephalitis	Authority website- EMA-PSUSA	(https://www.ema.europa.eu/en/documents/agenda/agenda-prac-meeting-2-5-june-2025_en.pdf)	June -25

CONCLUSION

Pharmacovigilance plays a critical role in safeguarding public health through the continuous monitoring and evaluation of adverse drug reactions and adverse events following immunization. This report provides an overview of ADRs and AEFIs reported in Lebanon during the reporting period, highlighting the importance of systematic data collection, analysis, and interpretation to identify potential safety concerns.

The findings underscore the need for sustained vigilance and collaboration among healthcare professionals, patients, marketing authorization holders, and the national pharmacovigilance system to ensure timely reporting and assessment of safety data. Strengthening reporting practices and signal management remains essential to minimizing risks associated with medicinal products and vaccines and to supporting informed regulatory decision-making aimed at protecting patient safety and improving therapeutic outcomes.

The high proportion of medication use-related reports, particularly involving antineoplastic and immunomodulating agents, highlights the need for strengthened risk-minimization measures, prescriber education, and patient counseling within the Lebanese healthcare context.

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