Annual Safety Analysis Report (ASAR)

PVGA in Egypt – 2025

JUL 2026

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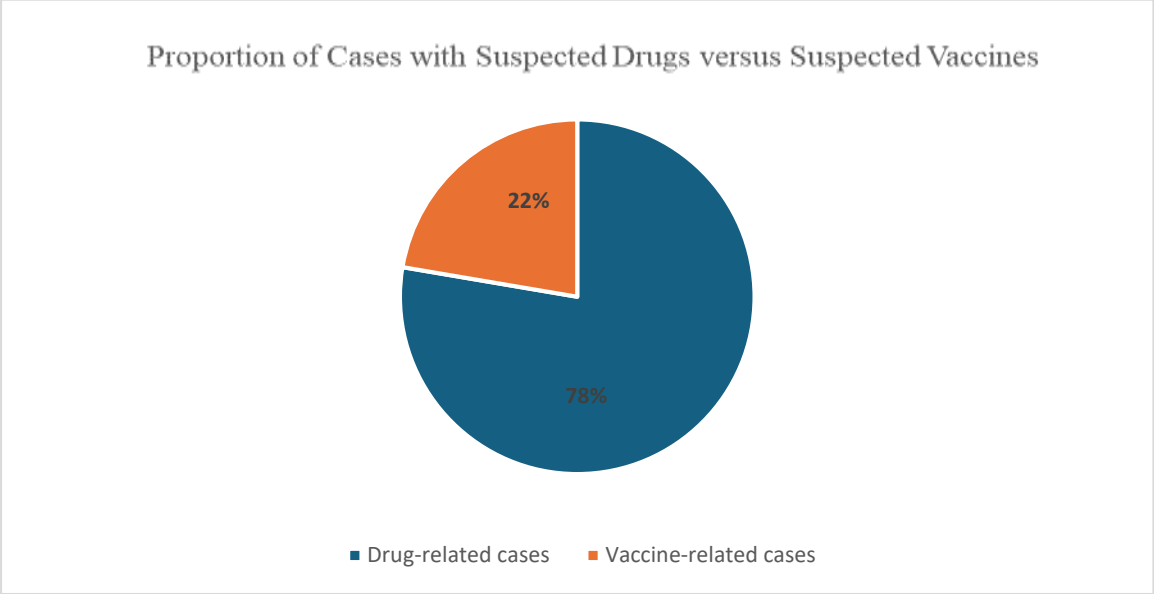
1. Overview:

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as "a drug-related event that is noxious and unintended and occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function (1). **The pharmacovigilance systems** allow identifying and preventing the risks associated with drug use, especially of recently commercialized drugs; they detect signals from data of the global ADR register and support decisions taken by regulatory agencies in different countries (2).

This report is prepared annually to help health professionals monitor and improve reporting systems in Egypt and ensure the safety and efficacy of pharmaceutical products.

2. Description of the total number of recorded adverse drug reactions (ADRs) cases in Egypt, 2025

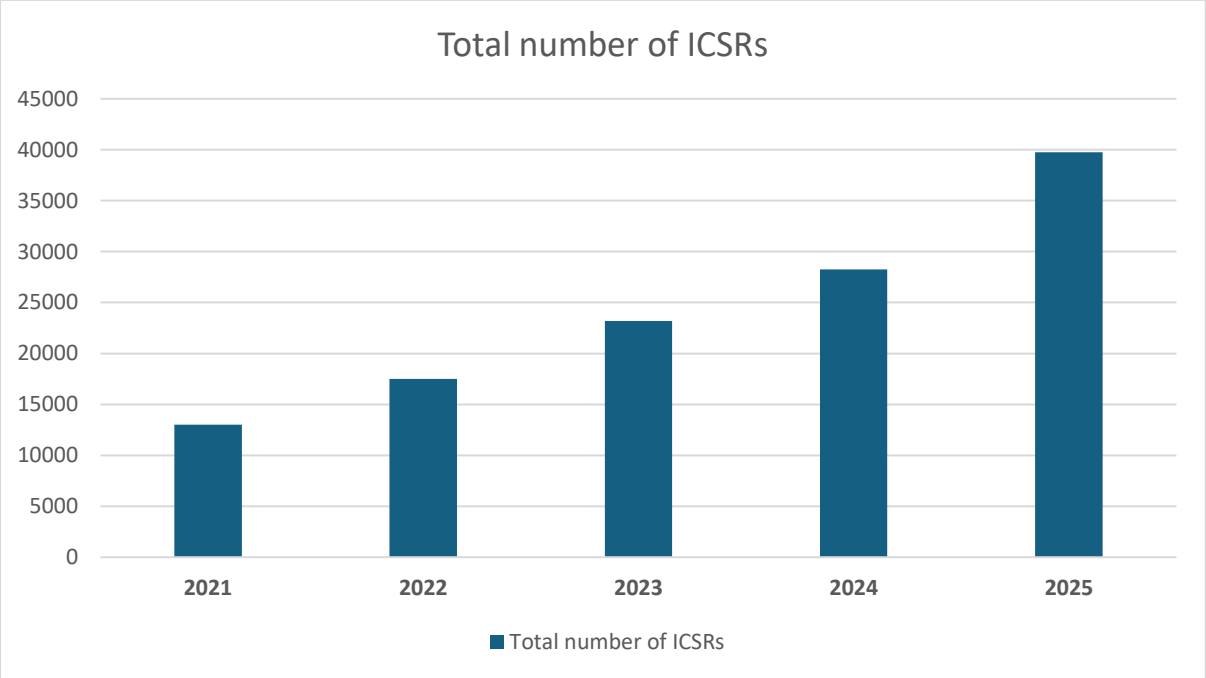
In 2025, Egypt recorded a total of **51,285** adverse drug reactions (ADRs) cases, comprising **39,767 cases where a drug was suspected** and **11,431 cases where a vaccine was suspected**. The breakdown and key trends are summarized below (VL dataset date: 05/07/2026).



1. Regarding the cases where a drug(s) was suspected (ICSRs)

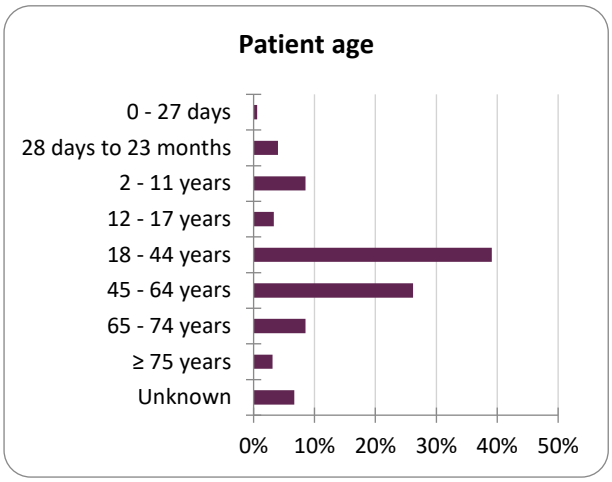
Monitoring the increase in ADR reporting is critical to drug safety and public health. It enables early detection of risks, informs regulatory decisions, and protects patients from harm. The Pharmaceutical Vigilance General Administration (PVGA) within the Egyptian Drug Authority (EDA) plays a crucial role in promoting an increase in the reporting rate by fostering a culture of reporting and continuous monitoring. This enables healthcare systems to ensure that products remain safe and effective for all users.

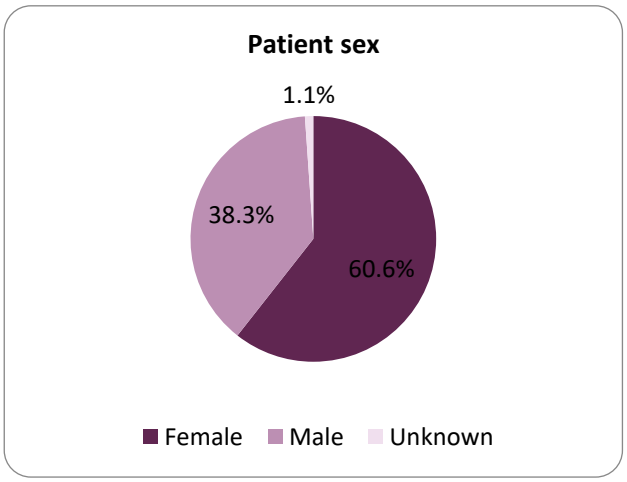
The increase in reporting rate of cases with suspected drugs over the past five years is presented as follows:



Over the past five years, there has been a consistent and notable increase in the reporting rate, reflecting the proactive efforts and key activities of the PVGA team in enhancing awareness and systematically collecting adverse drug reaction (ADR) reports from diverse sources. A marked increase in reporting activity was observed during the period 2021–2025, with the total number of reports rising by approximately 206%, from 13,012 to 39,767 cases with suspected drugs.

The total dataset of 39,767 cases where a drug was suspected in 2025.





The cases are classified into two main categories according to the seriousness criteria: **serious** and **non-serious cases.** The breakdown is a fundamental aspect of pharmacovigilance and offers insights into the proportion and severity of the cases. It ensures patient safety, regulatory compliance, efficient resource allocation, and informed decision-making, ultimately contributing to the safe and effective use of medications. Here's a detailed explanation of each category:

- **Serious: 7,537 cases (19.0%)**
- **Non serious: 32,230 cases (81.0%)**

The cases where a drug was suspected that ended with fatal outcomes were 620 cases, and the top reported terms (MedDRA PTs) were as follows:

Hypersensitivity (5.8%), Rash (5.7%), Erythema (5.6%), Drug ineffective (5.3%), Injection site erythema (5.2%), Dizziness (4.8%), Vomiting (4.7%), Dyspnoea (4.4%), Nausea (4.3%), Diarrhoea (4.2%), Abdominal pain upper (3.9%), Fatigue (3.8%), Pruritus (3.8%), Allergy test positive (3.5%), Headache (3.3%), Abdominal pain (3.2%), (3.0%).

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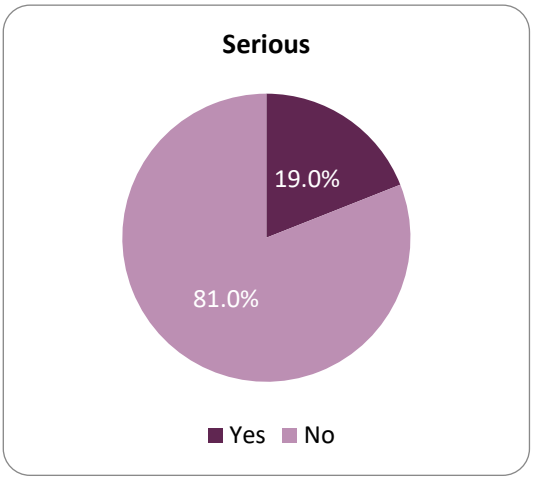
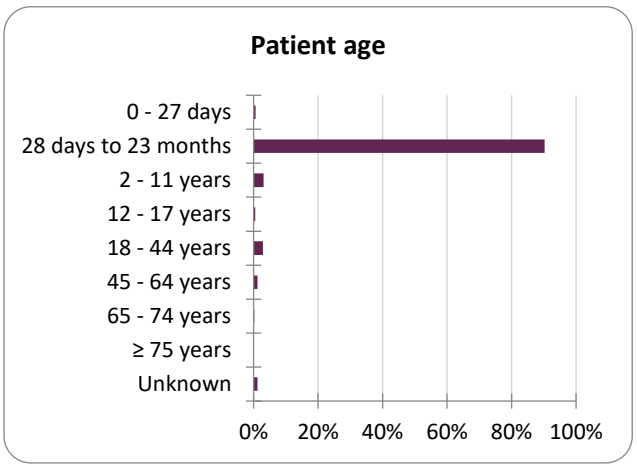
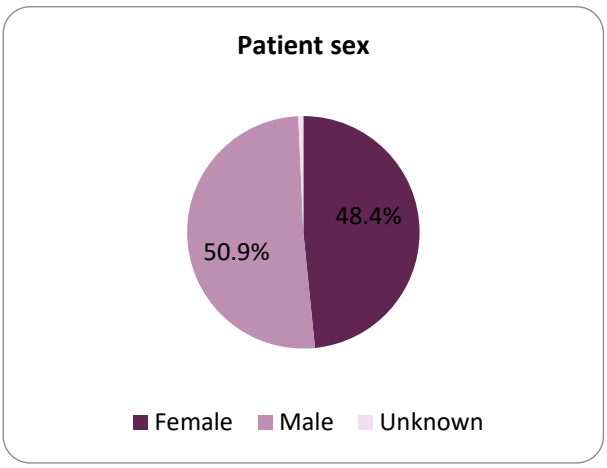


2. Regarding the cases where a vaccine(s) was suspected

The total dataset of 11,431 cases where a vaccine was suspected in 2025.

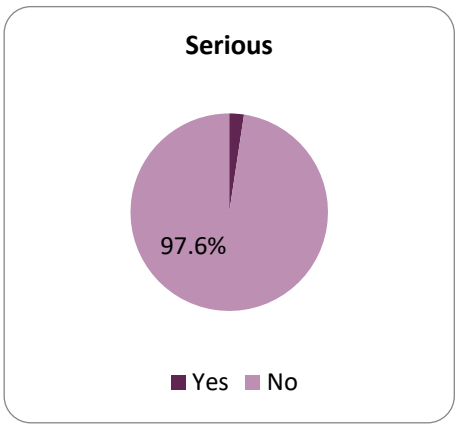




The majority of cases where a vaccine was suspected were observed among children aged 28 days to 23 months (90.2%), consistent with the national Expanded Programme on Immunization (EPI) schedule, in which children in this age group receive multiple routine immunizations. Furthermore, enhanced AEFI surveillance and active reporting practices implemented within EPI activities contribute substantially to the high proportion of cases with suspected vaccines captured in the national database.

The cases where a vaccine was suspected, classified by seriousness, are a cornerstone of effective pharmacovigilance and public health practice. It ensures patient safety, supports regulatory decision-making, and fosters public trust in immunization programs. Here's a detailed explanation of each category:

- **Serious: 272 cases (2.4%)**
- **Non serious: 11,159 cases (97.6%)**



The cases where a vaccine was suspected that ended with fatal outcomes were 5 cases, and the top reported terms (MedDRA PTs) were as follows: Pyrexia (49.3%), Vaccination site pain (22.6%), Crying (17.1%), Erythema (8.4%), Swelling (7.0%), Extensive swelling of vaccinated limb (3.7%), Fatigue (1.8%), Injection site erythema (1.7%), Rash (1.7%), Injection site swelling (1.6%).

3. Highlight the important Egyptian Pharmaceutical Vigilance General Administration (PVGA) Activities through 2025

The EDA plays a crucial role in leading the implementation of pharmacovigilance throughout the entire healthcare sector. There are notable achievements and ongoing efforts to enhance drug safety. Here are the highlights of the important PVGA activities to enhance PV awareness, listed as follows:

1. In line with the EDA's steadfast commitment to promoting a culture of pharmacovigilance and elevating medical awareness, PVGA delivered an exceptional series of awareness lectures throughout 2025, targeting healthcare professionals across various health sectors. The total number of lectures conducted during the year reached an impressive number of about 61 lectures, targeting a wide range of health institutions and entities, including the Ministry of Health and Population and its affiliated bodies, the Egyptian Healthcare Authority (EHA), university hospitals, private hospitals, and **university and postgraduate students.** These efforts reflect the EDA's dedication to disseminating Pharmacovigilance knowledge and promoting safe drug use.

2. In its pursuit of expanding cooperation and strengthening strategic partnerships, the EDA collaborated with **major institutions and stakeholders in the healthcare sector** to deliver a series of awareness lectures aimed at enhancing pharmaceutical knowledge and spreading pharmacovigilance culture. These partnerships included the **secretariat of Specialized medical centers, El-Salam International Hospital New Cairo, New Mansoura**

University, Cairo University, Ain Shams University, Shifa Hospital, Pharos University, German Saudi Hospital, 6 October University, and leading pharmaceutical companies, demonstrating the EDA's commitment to unifying efforts and fostering integration among various healthcare stakeholders. This ensures the highest standards of drug safety at both national and international levels.

3. In a significant step reflecting the EDA's commitment to developing and qualifying medical personnel according to the latest international standards, the authority **trained focal points from various health institutions** on the fundamental principles of pharmacovigilance. They were also trained in entering data into the **national safety surveillance system for collecting, managing, analyzing, and sharing adverse event data (VigiFlow)**, ensuring the highest levels of accuracy and transparency in reporting and analyzing drug-related risks. This contributes to building a safer and more effective pharmaceutical system at the national level.

4. As part of its ongoing efforts to build a qualified workforce, the EDA **trained a total of 4,422 healthcare professionals** through specialized training programs designed to enhance their skills and capabilities in handling medications and monitoring their adverse effects, in line with global best practices in this vital field.

5. EDA also focused on supporting and developing the role of pharmacists in the community. Together for Safe Medicine initiative, the 7th wave was launched, **an intensive training program targeting pharmacists working in community pharmacies and outpatient pharmacies in both government and private hospitals**. The initiative was launched by the PVGA to improve pharmaceutical services in Egypt, enhance pharmacists' professional competencies, promote patient safety, and support the implementation of pharmacovigilance activities in community pharmacies in line with Egypt Vision 2030.

This seventh wave of the program, with **125 pharmacists meeting the application requirements, and 96 completing all required training tasks,** and by the end of all conducted waves, thanks to the efforts of these dedicated pharmacists, **3517 reports** were submitted through the national database for adverse drug reactions, reflecting positive engagement and growing awareness of the importance of monitoring and tracking drug adverse effects.

6. EDA also focused on supporting and developing the role of pharmacists in the SMC, GOTHI, and SCOUH. Be Vigilant Initiative for central focal points inside health settings was launched, **an intensive training program aiming to increase adverse drug reaction reporting, maximize the capacity of central pharmacovigilance focal points within hospitals across diverse affiliations, and support healthcare facilities and users of the national database (Vigiflow).**

The initiative was formed of 10 lectures with the following content: Introduction to pharmacovigilance, evidence-based medical research, use of available tools for reporting adverse drug and vaccine reactions, adverse drug reaction reporting system using Vigiflow, classification of adverse reactions, the MedDRA global coding system, criteria for classifying the severity of adverse reactions, causal assessment of adverse drug and vaccine-related reactions, quality of adverse reaction reports and completeness score.

7. As part of **MedSafety Week**, the EDA's participation in MedSafety Week 2025 was marked by a massive collaborative campaign between the **EDA, the International Society of Pharmacovigilance (ISoP) Egypt Chapter, and the Uppsala Monitoring Centre (UMC)**.

   The 10th annual #MedSafetyWeek ran from November 3 to November 9, 2025, focusing on the theme *"We can all help make medicines safer."* The campaign featured widespread educational activities and safety awareness. EDA collaborated with UMC to actively promote the reporting of adverse drug reactions (ADRs) and to highlight how both healthcare professionals and the public can reduce preventable harm.

   They were also encouraged to actively participate in reporting any suspected adverse effects, ensuring the highest levels of safety and rational use of medications.

8. In line with its regulatory role of verifying the quality and safety of healthcare services, the EDA conducted **a series of field visits to several hospitals**, during which **11 detailed case investigations** were carried out in response to reported ICSRs. These efforts reflect the EDA's commitment to fulfilling its regulatory and oversight responsibilities to the fullest extent.

9. PVGA also has a role in simplifying the process of reporting ADRs systems through:
    - Providing user-friendly online platforms.
    - Providing various ways for reporting ADRs, which make it easier for the reporter to report, like a hotline and email for ADR reporting
    - User-friendly guidelines for ADR reporting are published on the EDA website.

4. PVGA Safety communications and Regulatory actions taken for safety reasons

Share PV data and trends through newsletters, journals, or websites to highlight the importance of reporting and tracking. These efforts are done to provide updates on safety actions taken due to PV reports, reinforcing their impact. The following is the highlighted activity of safety communications:

1. Different types of Safety Communications are done by the Emergency Safety Issues Unit (ESI) in PVGA as described below, as published on the EDA website.

* **DHPCs: 19**
* **Safety Alerts: 28**
* **Newsletter (ESI part): 12**
* **Product Cancellation: 3**

In Pharmacovigilance, the **DHPC (Direct Healthcare Professional Communication) letter** and **safety alerts** play critical roles in ensuring the safe use of medicinal products and protecting public health. DHPC letters and safety alerts are vital components of pharmacovigilance, ensuring that healthcare professionals and the public are informed about potential risks associated with medicinal products, thereby safeguarding patient health.

2. PVGA issues a monthly newsletter with a total of 12 newsletters in 2025 to disseminate important safety information, updates, and best practices related to drug safety. Monthly newsletters are a valuable tool in pharmacovigilance, fostering communication, education, and collaboration among stakeholders. By keeping everyone informed and engaged, they contribute to the overall goal of ensuring patient safety and improving public health.
3. A Regulatory Action Taken for Safety Reasons is any measure mandated or requested by a regulatory authority to mitigate, reduce, or eliminate a known or potential public health risk associated with a marketed or investigational product. The core purpose of these actions is to protect the public by ensuring that the benefits of a product continue to outweigh its risks, or by removing a high-risk, defective, or contaminated product from the market.
4. There are many regulatory actions in 2025 initiated by the ESI unit, as follows:

   - Pharmaceutical product cancellation, for example, products containing pipazethate & Obeticholic acid
   - Restrictions on the use of some pharmaceutical products, for example: Products containing levamizole.

5. Training programs

A. Annual Pharmacovigilance Training Program

During 2025, the PVGA continued its commitment to strengthening pharmacovigilance capacity through the implementation of its annual training program, targeting pharmaceutical companies, healthcare professionals, students, and other relevant stakeholders. The training activities covered a wide range of topics, including medical device vigilance, pharmacovigilance systems and Pharmacovigilance System Master File (PSMF) requirements, adverse drug reaction (ADR) reporting and MedDRA coding, signal detection and management, emerging safety issues, regulatory intelligence, safety reporting obligations, periodic benefit risk evaluation report (PBRER) assessment and requirements, and the development of PV standard operating procedures in accordance with Good Pharmacovigilance Practices (GVP). These programs combined theoretical knowledge with practical exercises to enhance participants' competencies in safety monitoring, risk assessment, data quality, and regulatory compliance. By strengthening stakeholders' understanding of national and international PV requirements, these initiatives contributed to improving the quality and timeliness of safety reporting, supporting proactive signal

management, enhancing regulatory compliance, and ultimately promoting patient safety and public health outcomes in Egypt.

B. Participation in Specialized Training Programs and Capacity-Building Activities

As part of its commitment to continuous professional development and the enhancement of pharmacovigilance practices, PVGA representatives actively participated in and contributed to several specialized national and international training programs and awareness activities during 2025, either as trainers, facilitators, or attendees. These activities provided valuable opportunities for knowledge exchange, capacity building, and alignment with evolving international pharmacovigilance standards and best practices. Key activities included:

1- Advanced Approaches in Pharmacovigilance Evaluations and Inspection (Egypt, 4-8 May 2025)

A specialized training program contacted by EDA experts and delivered to National Center for Pharmacovigilance and Drug Safety (Aden, Yemen) focused on advanced pharmacovigilance evaluation and inspection practices, including PSMF assessment, RMP and PBRER evaluation, signal management, post-marketing surveillance, pharmacovigilance inspections, and CAPA implementation, strengthening regulatory oversight and compliance with global pharmacovigilance standards.

2- **Egyptian Drug Authority Participation in an Awareness Event to Strengthen AEFI Reporting (Vacsera, Egypt, 25 June 2025).**

PVGA representatives actively participated in a specialized awareness event aimed at strengthening the reporting of Adverse Events Following Immunization (AEFIs) among healthcare professionals. The event focused on enhancing awareness of vaccine safety monitoring, improving reporting practices, promoting accurate case documentation, and fostering collaboration among healthcare providers and relevant stakeholders. Through scientific presentations and interactive discussions, the participation contributed to reinforcing pharmacovigilance activities, supporting patient safety, and advancing a more effective and responsive immunization safety system.

3- Periodic Benefit–Risk Evaluation Report (PBRER) Assessment Workshop (WHO, Cairo, 22–23 October 2025)

The workshop focused on strengthening regulatory capacity in the assessment of PSURs/PBRERs in accordance with international standards, including ICH E2C(R2) and EU GVP Module VII. Through practical exercises and real-case assessments, participants enhanced their benefit–risk evaluation skills to support evidence-based regulatory decision-making and promote alignment with WHO, EU, and other international pharmacovigilance best practices.

4- Training Program on MedDRA Coding and Safety Data Analysis Using MedDRA (MedDRA MSSO, 11–14 November 2025)

The training program, which was implemented in two phases, addressed the mechanisms for the optimal use of the MedDRA international medical terminology system in coding medical information and analyzing pharmacovigilance data according to ICH requirements. It also included intensive practical training on applying internationally approved reference documents, contributing to the enhancement of professionals' competencies in this field within Egypt

6. PVGA participation in global and national Conferences and Scientific Events

The EDA also made notable efforts to represent Egypt on the international stage. It actively participated in the following international conferences/workshops:

1. **Participation in the First Pharmacovigilance Technical Committee Meeting of AUDA-NEPAD** Kigali, Rwanda,10–11 February 2025.
   The PVGA actively contributed to discussions on strengthening pharmacovigilance systems across Africa and fostering regional collaboration.

2. **Participation in the AU-3S Signal Validation Hub, Safety Surveillance Signal Validation Training Program** – Kigali, Rwanda, 13–14 February 2025.
   The workshop organized by AUDA-NEPAD, included specialized training delivered by experts from the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) on signal detection, validation, assessment, and management methodologies. The Egyptian team presented the national **"Signal Management Process"**, highlighting local procedures for signal detection, validation, assessment, and regulatory decision-making, which received positive recognition from MHRA representatives. The workshop contributed to strengthening national expertise in signal management and promoting alignment with international pharmacovigilance best practices.

3. **Participation in MedDRA Optimization Training under the AU3S Program** – Cape Town, South Africa, 24–25 February 2025.
   PVGA representatives received an advanced workshop on capacity strengthening on the use of MedDRA packages for pharmacovigilance and regulatory activities.

4. **Participation in the PMDA-ATC Pharmacovigilance Seminar** – 26–28 February 2025.
   Organized by Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the seminar provided advanced training on international pharmacovigilance practices, with active participation from PVGA representatives.
   PV representatives contributed to international discussions and collaborative group exercises focused on signal detection, causality assessment, risk classification, and the development of appropriate risk minimization and additional pharmacovigilance activities. Furthermore, Egypt shared its regulatory experience and engaged with experts from different countries, promoting knowledge exchange and strengthening regulatory approaches to ensuring the safe and effective use of medicines.

5. **F2F workshop in signal assessment, conducted by Uppsala Monitoring Center (UMC), Uppsala, Sweden, from 19-23 May 2025**.

A representative of the PVGA in the signal management unit actively participated in a face-to-face workshop on signal assessment, where practical training was provided under the supervision of experts and instructors from the Uppsala Monitoring Centre (UMC). During the workshop, the representative conducted a comprehensive assessment of a nationally detected drug–adverse event combination, including case series evaluation, evidence review, and causality assessment in accordance with internationally recognized pharmacovigilance methodologies.

The outcomes of this signal assessment exercise contributed to strengthening PVGA's signal management capabilities and were subsequently disseminated through scientific presentation at the 24th Annual Meeting of the International Society of Pharmacovigilance (ISoP), held in Cairo, Egypt, from 22–24 October 2025, demonstrating the PVGA's commitment to advancing evidence-based pharmacovigilance practices and international knowledge sharing.

6. **Participation in WHO workshop on the implementation of guidelines on regulatory preparedness for the oversight of pandemic or other emergency-use vaccines in importing countries- Bangkok, T**hailand, June 2025.

A PVGA representative actively participated in the WHO workshop on regulatory preparedness for health emergencies held in Thailand, contributing to discussions on vaccine regulation, emergency use authorization frameworks, pharmacovigilance systems, and international best practices. The participation supported knowledge exchange with global regulatory authorities and reinforced efforts to strengthen regulatory readiness, vaccine safety monitoring, and regional collaboration in line with WHO standards.

7. **Participation in the AUDA-NEPAD Technology Onboarding Workshop for Wave 2 countries** – Lusaka, Zambia, 25–27 August 2025.
   This workshop represents a key milestone in aligning national stakeholders from the Democratic Republic of Congo, Egypt, Mozambique, Rwanda, Senegal, Tanzania, and Uganda with the AU-3S cross-country safety monitoring platform. The workshop will support capacity building on the Safety Connect system, address technical gaps in safety data management and migration, and promote regional and learning from Wave 1 countries.

8. **Participation in the AU-3S Signal Validation Hub, Signal Management Workshop** – Nairobi, Kenya, 2–4 September 2025.
   The workshop focused on the assessment and validation of safety signals identified from the African adverse event database, particularly those related to priority medicinal products in Africa. During the workshop, EDA representatives actively participated in collaborative signal assessment exercises and contributed to the scientific evaluation and validation of several potential safety signals. Furthermore, EDA representatives continue to participate as observers in the periodic virtual meetings of the AU-3S Signal Validation Hub, where experts from participating countries discuss emerging safety signals, share assessment outcomes, and review ongoing signal detection and validation activities. These engagements have strengthened national expertise in signal assessment, promoted regional collaboration, and supported the harmonization of pharmacovigilance practices across African regulatory authorities.

9. **Active Participation in the ISoP Cairo 2025 Annual Conference from 24-27 October 2025**.

Representatives from the Pharmaceutical Vigilance General Administration (PVGA), Egyptian Drug Authority (EDA), actively participated in the Annual Conference of the International Society of Pharmacovigilance (ISoP), held in Cairo from 24–27 October 2025.

The Manager of Pharmaceutical Vigilance General Administration (PVGA), participated as a panel speaker and delivered an oral presentation highlighting the administration's role in monitoring and assessing post-marketing drug safety, promoting adverse drug reaction reporting culture, and showcasing recent developments in pharmacovigilance activities in Egypt.

The PVGA team also presented four scientific abstracts, three of which resulted from potential safety signal evaluations conducted by the safety signals management unit team in the PVGA. The topics included:

- A Potential Signal of **Seizure** Associated with the Administration of **Pipazetate, which is presented as a poster presentation.**
- A Potential Signal of **Osteonecrosis** Associated with the Administration of **Fingolimod, which is presented as a poster presentation.**
- **Evaluating Liver-Related Risks of Nitazoxanide**: Findings from Egyptian Post-marketing PV Case Reports**, which is presented as an oral presentation.**

- The fourth abstract addressed the role of **artificial intelligence in pharmacovigilance**, resulting from a collaboration between an EDA representative and the ISoP Artificial Intelligence Special Interest Group**, which is presented as a poster presentation.**

This active participation reflects the EDA's commitment to promoting transparency, sharing scientific expertise, and strengthening Egypt's role as an active contributor within the global pharmacovigilance community.

10. **Participation in the 43rd Annual Meeting of the WHO-Program for International Drug Monitoring (WHO-PIDM)** – October 2025.

The Egyptian Drug Authority (EDA) participated in several workshops and panel discussions held as part of the 43rd Annual Meeting of the World Health Organization Program for International Drug Monitoring (WHO PIDM), organized by the World Health Organization in Cairo under the theme, "Leaving No One Behind: Pharmacovigilance for Women of Childbearing Age and Children." The participation took place within the framework of the Arab Republic of Egypt's hosting of this global event.

During the meeting, the Central Administration of Pharmaceutical Care at the Egyptian Drug Authority contributed to the management of a session focused on Risk Management Plans in the field of pharmacovigilance.

11. **Participation in CEPSA Mentoring and Research & Policy Support Programs workshop**
    Aiming to strengthen knowledge, training, and research in pharmacovigilance. Through capacity building, awareness creation, and knowledge sharing, the training also aims to support health systems, healthcare professionals, and communities across the region.

7. Conclusion and Recommendations

The results of 2025 demonstrate the continued strengthening of Egypt's pharmacovigilance system and its vital role in protecting public health. The significant increase in adverse drug reaction reporting reflects the success of awareness campaigns, training programs, stakeholder engagement, and improved reporting mechanisms. Continuous monitoring and evaluation of safety data enabled the identification and assessment of important safety concerns, resulting in six safety signals reaching the status of "Assessed for action" and supporting evidence-based regulatory decision-making.

The implementation of appropriate regulatory measures, including DHPCs, safety alerts, product recalls, product cancellations, and restrictions on product use, highlights the effectiveness of the national pharmacovigilance system in ensuring that the benefits of medicines and vaccines continue to outweigh their risks. Furthermore, national training programs and active participation in regional and international pharmacovigilance initiatives

contributed to strengthening regulatory capacity, enhancing technical expertise, and aligning Egypt's pharmacovigilance practices with international standards.

Recommendations for continuous improvement for ADR reporting are as follows:

To further strengthen the national pharmacovigilance system and ensure sustainable improvements in medicine and vaccine safety monitoring, the following recommendations are proposed:

- Continue expanding pharmacovigilance awareness campaigns targeting healthcare professionals, patients, academic institutions, and the general public to further enhance the reporting culture.

- Strengthen capacity-building programs through regular training and advanced workshops on signal detection, risk assessment, benefit–risk evaluation, and pharmacovigilance inspections.

- Promote the quality and completeness of ICSRs to improve signal detection and evidence-based decision-making.

- Enhance the use of digital technologies and data analytics tools to support efficient safety data management, signal detection, and risk monitoring activities.

- Expand collaboration with national and international stakeholders, including regulatory authorities, public health programs, academic institutions, and international organizations, to facilitate knowledge exchange and adoption of best practices.

- Continue strengthening signal management activities and proactive safety surveillance to ensure the timely identification, assessment, communication, and mitigation of emerging safety risks.

- Maintain and further develop risk communication activities, including safety alerts, DHPCs, newsletters, and public awareness campaigns, to ensure timely dissemination of important safety information.

- Support ongoing participation in international pharmacovigilance networks, training programs, and scientific meetings to maintain alignment with evolving global standards and regulatory expectations.

8. References

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