Annual Safety Analysis Report (ASAR)

PVGA in Egypt – 2024

JUL 2026

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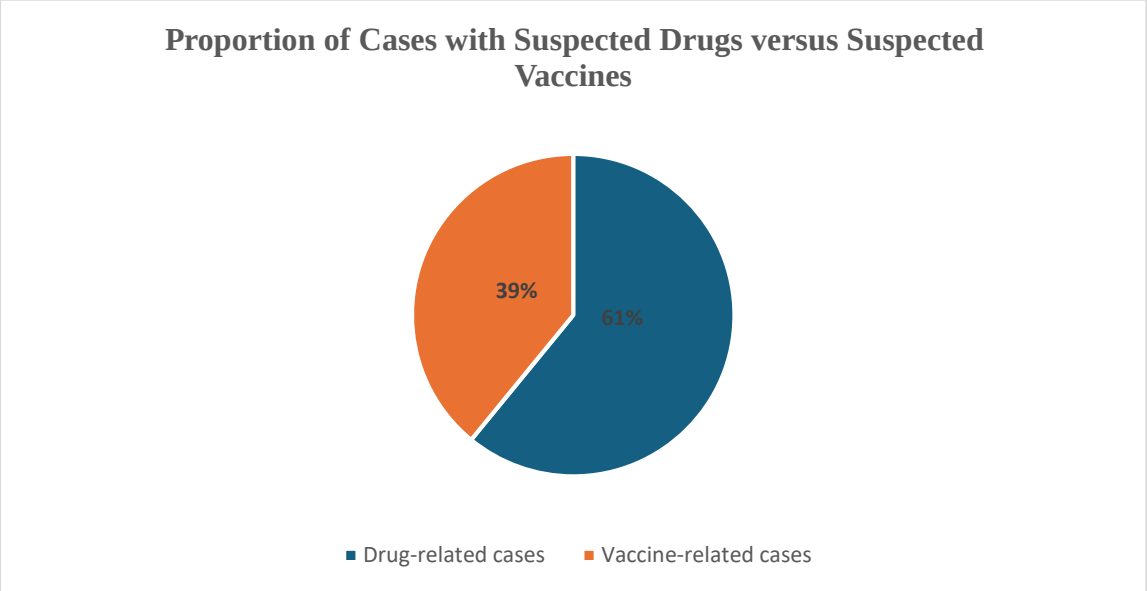
1. Overview:

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 healthcare professionals and other relevant stakeholders 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, 2024

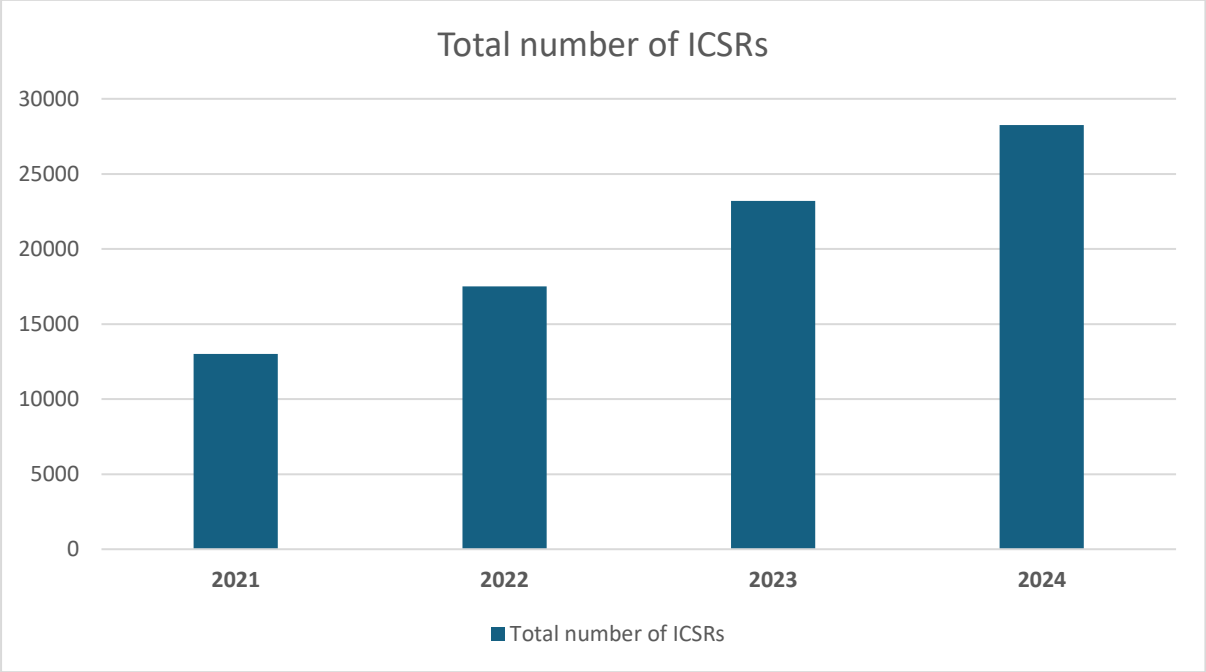
In 2024, Egypt recorded a total of **46,518** adverse drug reactions (ADRs) cases, comprising **28,259 cases where a drug was suspected** and **18,127 cases where a vaccine was suspected** (VL dataset date: 30/06/2026). The breakdown and key trends are summarized below:



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

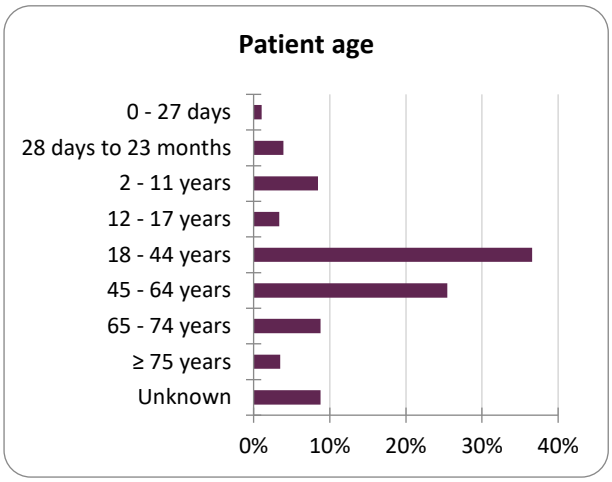
Monitoring the increase in ADR reporting is critical to drug safety and public health. It enables early detection of risks, informs regulatory decisions, and protects patients from harm. The Pharmaceutical Vigilance General Administration (PVGA) within the Egyptian Drug Authority (EDA) plays a crucial 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.

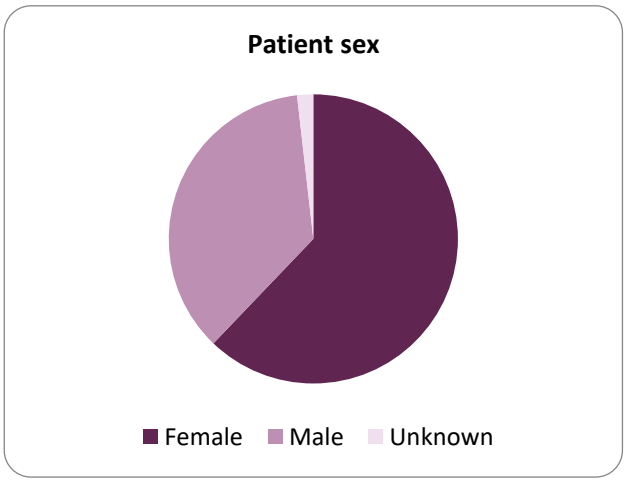
The increase in reporting rate in the cases where a drug was suspected, over the past four years is presented as follows:



Over the past four 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.

The total dataset of 28,259 cases where a drug was suspected in 2024.





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: 6,217 cases (22.0%)**
- **Non serious: 22,042 cases (78.0%)**

The cases where the drug was suspected that ended with fatal outcomes were 567 cases, and the top reported terms (MedDRA PTs) were as follows:

Rash (5.4%), Erythema (5.4%), Drug ineffective (6.0%), Hypersensitivity (4.7%), Vomiting (4.7%), Diarrhoea (4.2%), Headache (4.2%), Off label use (4.1%), Abdominal pain upper (4.0%), Dyspnoea (4.0%), Dizziness (4.0%), Nausea (3.7%), Pruritus (3.7%), Fatigue (3.6%), Injection site erythema (3.5%), Allergy test positive (3.1%).

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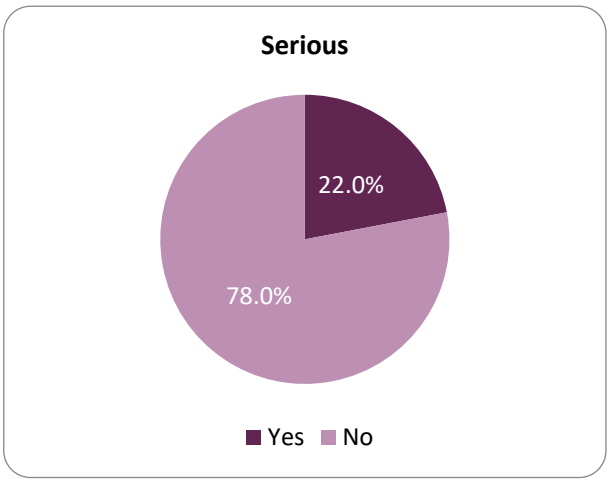
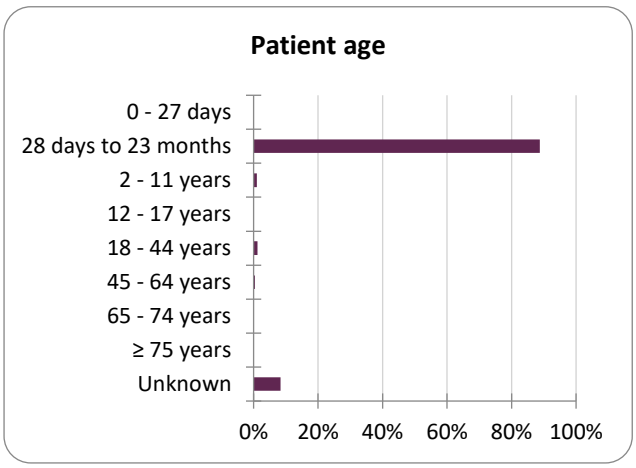
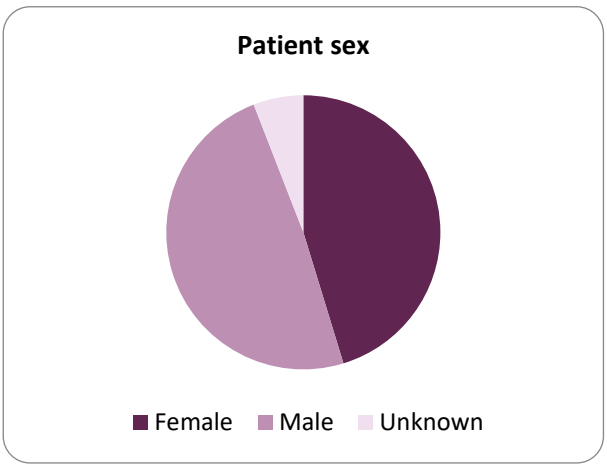


2. Regarding the cases where a vaccine(s) was suspected.

The total dataset of 18,127 cases where a vaccine was suspected in 2024.





The ADRs of 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, improves vaccine development, and fosters public trust in immunization programs. Without such classification, it would be challenging to manage risks effectively and maintain the overall benefits of vaccination. Here's a detailed explanation of each category:

- **Serious: 253 cases (1.4%)**
- **Non serious: 17,874 cases (98.6%)**

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 (56.2%), Swelling (19.9%), Erythema (19.5%), Crying (13.3%), Body temperature increased (8.6%), Skin swelling (2.8%), Injection site swelling (2.0%), Vaccination site pain (2.0%), Injection site erythema (1.5%), Extensive swelling of vaccinated limb (1.4%).

3. Highlight the important Egyptian Pharmacovigilance General Administration (PVGA) Activities through 2024

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 2024, targeting healthcare professionals across various health sectors. The total number of lectures conducted during the year reached an impressive number of about 50 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, the Egyptian Ministry of Interior, 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 Egyptian Ministry of**

Interior, Elnahda University, Elgalala University, the Egyptian Russian University (ERU), 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 liaison officers 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 4,284 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. Pharmaceutical care initiative was launched, **an intensive training program targeting pharmacists working in community pharmacies and outpatient pharmacies in both government and private hospitals**.

The program aimed to spread pharmacovigilance culture among pharmacists, patients, and their families. This training program was conducted in three waves (the fourth (continuation), fifth, and sixth waves) during 2024, with **320 pharmacists meeting the application requirements, and 167 successfully completing all required training tasks**. Thanks to the efforts of these dedicated pharmacists, **1,905 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. As part of **MedSafety Week**, the EDA launched an intensive awareness campaign that included **pharmacovigilance awareness sessions for approximately 10000 patients and their relatives**, **2 scientific days, and 71 orientation sessions delivered to the healthcare professionals.** These activities took place from **November 4 to November 10, 2024**, and had a significant impact on enhancing the understanding of healthcare professionals and the community about the importance of pharmacovigilance. They were also encouraged to actively participate in reporting any suspected adverse effects, ensuring the highest levels of safety and rational use of medications.

7. In line with its regulatory role to verify the quality and safety of healthcare services, the EDA conducted a series of field visits to several hospitals, where 34 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. 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 **22 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.

8. 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

Sharing 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 in PVGA as described in the figure below, as published on the EDA website.

    * **DHPCs: 14**
    * **Safety Alerts: 31**
    * **Newsletter (ESI part): 12**
    * **Product Cancellation: 8**

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 2024 to disseminate important 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 a product's benefits 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 2024 initiated by the ESI unit, as follows:

- DHPCs initiated by the ESI unit as
  - Risperidone oral solution formulation-Risk of accidental overdose following administration errors, which RRAs have published as Sweden & HPRA after being published by EDA
  - Hydroxychloroquine-Potential risk of major congenital malformations and new risks
- Pharmaceutical product cancellation, for example, products containing Ataluren & Obeticholic acid
- Restrictions on the use of some pharmaceutical products, for example: Products containing Promethazine

5. Training programs

Through 2024, the PVGA conducted a series of comprehensive training programs to enhance pharmacovigilance practices. These initiatives aimed to strengthen the capabilities of healthcare professionals, pharmaceutical companies, and regulatory bodies, ensuring compliance with international standards and improving patient safety. The most important training programs in 2024 are highlighted as follows:

1. **Medical Device Vigilance Training**

- Focused on the safety monitoring of medical devices, covering requirements for vigilance files, incident reporting mechanisms, and post-market surveillance.
- Emphasized compliance with updated safety regulations, including the mandatory appointment of qualified PV specialists.

2. **Pharmacovigilance Systems Master File Training**

- Provided integrated knowledge on PV systems, from pre-licensing to post-market drug safety monitoring.
- Included practical applications of PV components, ensuring participants could effectively evaluate and report adverse drug reactions (ADRs).

3. **Emerging Safety Topics and Regulatory Research**

- Addressed new safety issue concerns, methods for searching on reference regulatory authority websites, and regulatory timelines for submitting safety updates.
- Highlighted the importance of compliance with PV requirements and the consequences of non-compliance.
- Trained participants on drafting PV-specific standard operating procedures (SOPs) to align with Good Pharmacovigilance Practices (GVP).

4. **ADR Reporting and MedDRA Coding**

- Covered optimal practices for ADR reporting, including vaccine- and cosmetic-related adverse events.
- Featured hands-on training in MedDRA coding to standardize terminology in safety reports.

5. **Signal Detection and Management**

- Covered methodologies for detecting and assessing safety signals from diverse sources, with practical exercises in MedDRA coding, and safety data analysis using the MedDRA application.

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 Gulf Regulatory Affairs Summit – Dubai (23–25 April 2024)** A key regional forum discussing the latest pharmaceutical regulatory updates in the Gulf region. PVGA presented the Egyptian experience in strengthening pharmacovigilance systems and regulatory collaboration, aligning with EDA's vision to foster cross-border regulatory harmonization.
2. **WHO Eastern Mediterranean Regional Meeting – Doha (13–15 May 2024)** This regional meeting focused on assessing pharmacovigilance systems across the region and setting regional safety priorities.
3. **Africa Health ExCon – Cairo,** PVGA submitted and presented an abstract highlighting Egypt's experience in implementing electronic safety newsletters, detailing the phases of the project and key published outcomes. This reflects PVGA's innovative approach to digital communication and EDA's national awareness strategy.

4. **Meetings with the General Authority for Healthcare and JICA (Japan International Cooperation Agency)**, These meetings focused on enhancing collaboration in pharmaceutical safety and healthcare delivery. PVGA presented its role in early warning systems and ADR surveillance, supporting EDA's efforts to align with international best practices.

5. **AU3S Continental Working Group Meetings – Cairo (13–14 August 2024)**, PVGA took part in supporting the establishment of the African Union Technical Pharmacovigilance Committee and the AU-PRAC (Pharmacovigilance Risk Assessment Committee), hosted in Cairo. This reflects Egypt's leadership through EDA in shaping the African Medicines Agency's safety frameworks.
6. **FAO and Ministry of Agriculture Workshop – August 2024**, A workshop was organized in coordination with the Food and Agriculture Organization (FAO) and the General Authority for Veterinary Services, focusing on establishing a routine system for collecting and analyzing antimicrobial consumption data in veterinary use. PVGA contributed technical expertise, supporting national antimicrobial resistance (AMR) strategies.
7. **ICMRA Virtual Forum on Rare Diseases Medicines – September 2024** An international forum addressing regulatory and safety challenges for rare disease treatments. PVGA shared Egypt's regulatory perspective and progress in this area, aligning with EDA's efforts to ensure safe access to orphan drugs.
8. **WHO Virtual Meeting on Falsified and Adulterated Medicines – October 2024** Organized by WHO's Risk Communication Group, this forum focused on strategies for effective public communication regarding falsified medicines. PVGA presented Egypt's proactive systems for public reporting and risk mitigation, reflecting EDA's role in public health protection.
9. **Participation in ICDRA 2024 – India**, The International Conference of Drug Regulatory Authorities (ICDRA) gathered global regulators to discuss drug safety, governance, and innovation. PVGA, as part of the EDA delegation, presented national initiatives such as electronic newsletters and digital ADR reporting, promoting regulatory best practices.
10. **AfriSummit - October 2024**,
    A continental platform focused on strengthening African health systems. PVGA showcased Egypt's leadership in building a robust pharmacovigilance infrastructure and its active engagement in AUDA-NEPAD initiatives, in close coordination with EDA.

11. **DIA Rare Diseases Conference, November 2024**, PVGA participated in a panel discussion on the regulation and distribution of rare disease medicines in Egypt. The session highlighted the national efforts to ensure their availability and monitor their safety, aligned with EDA's regulatory framework.
12. **National Cancer Institute Conference-November 2024**, PVGA delivered a lecture on the newly developed pharmacist guidance for radiation therapy, demonstrating its contribution to clinical practice improvement. This aligns with EDA's mission to support rational drug use and healthcare professional education.

7. Conclusion and Recommendations

In 2024, PVGA made significant progress in ADRs monitoring, collection, and assessment, with 46,518 ADR cases recorded (28,259 cases with suspected drugs and 18,127 cases with suspected vaccines). The PVGA's efforts in awareness campaigns, training programs, and regulatory actions have strengthened drug safety monitoring and reporting systems. Despite these advancements, challenges remain in enhancing reporting rates and addressing serious ADRs.

Recommendations for continuous improvement for ADR reporting are as follows:

- **Enhance Reporting Systems:** Expand digital platforms and simplify ADR reporting tools to encourage broader participation from healthcare professionals and the public.
- **Targeted Training:** Focus on high-risk groups and regions to improve ADR recognition and reporting, especially for serious and fatal cases.
- **Public Awareness:** Launch nationwide campaigns to educate patients and caregivers on the importance of reporting ADRs.
- **Regional Collaboration:** Strengthen partnerships with African and international pharmacovigilance networks to share best practices and data.
- **Regulatory Vigilance:** Continuously monitor emerging safety signals and enforce timely regulatory actions to mitigate risks.

These steps will further solidify Egypt's pharmacovigilance framework, ensure safer medication use, and better public health outcomes.

8. References

1. Safety-of-medicines--adverse-drug-reactions-jun18.pdf [Internet]. [cited 2025 Feb 19]. Available from: https://www.who.int/docs/default-source/medicines/safety-of-medicines--adverse-drug-reactions-jun18.pdf?sfvrsn=4fcaf40_2

2. Montané E, Santesmases J. Adverse drug reactions. Med Clin (Barc). 2020 Mar 13;154(5):178–84.