ICSRs frequently asked questions

What is pharmacovigilance?

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

What are the specialties of pharmacovigilance?

- Pharmaceutical products
- Biological products
- Medical devices/supplies
- Herbal products
- Cosmetics
- Disinfectants/pesticides

What is the Egyptian Centre for Pharmacovigilance?

The Egyptian Pharmacovigilance Centre (EPVC) is part of the Egyptian Drug Authority and is responsible for monitoring the safety of pharmaceutical products. It follows the World Health Organization (WHO).

What is an adverse drug reaction (ADR)?

A noxious and unintended response to a pharmaceutical product. Contrary to an adverse reaction, an ADR is characterized by the suspicion of a causal relationship between the medicine and the occurrence, i.e. judged as being at least possibly related to treatment by the reporting or a reviewing health professional.

What is an adverse event following immunization (AEFI)?

This is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding, a symptom or a disease.

What is a serious adverse drug reaction?

A serious adverse drug reaction is an adverse reaction that may lead to one of the following outcomes:

- Death
- Permanent disability
- Life-threatening condition
- Requires hospitalization or prolongs a hospital stay
- Causes congenital malformations
- Requires medical intervention

Who can report an adverse reaction?

- Physicians, nurses, pharmacists, dentists, and other healthcare providers
- Patients and their relatives
- Pharmaceutical companies

What is the importance of reporting adverse drug reactions?

Reporting is crucial so the Egyptian Drug Authority can ensure the availability of effective and safe medications for the Egyptian public. This requires a post-registration pharmacovigilance system to monitor drug safety, in accordance with WHO guidelines.

Is the person who reports an adverse reaction held responsible?

No, the person who submits a report does not have any responsibility or consequences.

What action will be taken regarding the drug that harmed me?

Reports submitted to the Egyptian Pharmacovigilance Centre (EPVC) are assessed by responsible pharmacists. The reporter may be contacted for additional information. The report is then entered into the national adverse drug reaction database. The center's goal is to gain more information about the safety of pharmaceutical products and discover new adverse reactions based on the collected data.

If any new information is found, it will be shared with healthcare providers and, in some cases, patients.

What action will be taken regarding a suspected substandard or counterfeit drug that caused an adverse reaction?

Pharmacists at the Egyptian Pharmacovigilance Centre (EPVC) will review the submitted complaint and may contact you to obtain any missing information. Subsequently, the relevant departments will be informed to take the necessary actions, which may include one or more of the following steps:

- Reviewing the company involved in the report
- Withdrawing samples from the company
- Collecting samples from the complaint location for analysis and verification of compliance with specifications

Please retain the suspicious package to provide the information printed on it when requested.

Hot to submit the ICSR?

First: Reporting Adverse Drug Reactions in Relation to the Use of Pharmaceutical Products:

- **E-mail**

Pv.followup@edaegypt.gov.eg

- **Website**

https://vigiflow-eforms.who-umc.org/eg/med

- **Hotline**

15301

- **Hand by hand**

Address: 21, Abd El Aziz Al Soud street, El Manial, Cairo

- **QR code for E-reporting**

Second: Reporting Adverse Drug Reactions from Pharmaceutical Companies

Link:https://docs.google.com/spreadsheets/d/1adYrpgrosJCsZud7tZurhdiyZbfzIqX6D4llxsIVdKY/edit?gid=2002973239#gid=2002973239

Third: Reporting Adverse Drug Reactions in Relation to the Use of vaccines:

Contacting the Ministry of Health and Population by phone:

Hotline: 105