Central Administration of Pharmaceutical Care
General Administration of Pharmaceutical Vigilance

Guidance

Egyptian Guidance for Detecting & Reporting of Adverse Reactions For Pharmaceutical products and Medical Devices

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Table of Contents

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- **List of Abbreviations:**

- ADR: Adverse Drug Reaction
- AE: Adverse Event
- EDA: Egyptian Drug Authority
- EPVC: Egyptian Pharmaceutical Vigilance Center
- FSCAs: Field Safety Corrective Actions (FSCAs)
- ICSR: Individual Case Safety Report
- MAH: Market Authorization Holder
- PIDM: Program for International Drug Monitoring
- PVGA: Pharmaceutical Vigilance Gerenral Administration
- UMC: Uppsala Monitoring Center
- WHO: World Health Organization

Glossary

Abuse of a medicinal product Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.

Adverse Event/ Adverse Experience: An adverse event is any untoward medical occurrence in a patient exposed to a medicinal product and which does not necessarily have a causal relationship with the medicinal product. An adverse event can therefore be any unfavourableunfavorable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered causally related to this medicinal product.

Adverse Drug Reaction (ADR): Anoxious and unintended response to a pharmaceutical product. response to a medicinal product which is noxious and unintended Contrary to an adverse reactionevent, 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.

Adverse event of special interest: An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or programme, for which ongoing monitoring and rapid communication by the investigator to the sponsor may be appropriate. Such an event may require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties may also be needed (e.g., regulators).

Causality assessment: The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according established algorithms. The UMC system has been developed in consultation with the National CentresCenters participating in the Programme for International Drug Monitoring and is meant as a practical tool for the assessment of case reports. It is basically a combined assessment taking into account the clinical-pharmacological aspects of the case history and the quality of the documentation of the observation.

Drug/Medicine: Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. The term drug/medicinal product is used in a wider sense to include the whole formulated and registered product, including the presentation and packaging, and the accompanying information.

De-challenge: The withdrawal of a medicine from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.

- A positive de-challenge means:
  The adverse reaction improves or disappears after discontinuation of the suspected product.
- A negative de-challenge means:
  The reaction does not improve after stopping the product.

Expectedness of the adverse drug reaction: The expectedness of the reaction is assessed in accordance with the approved product information; the reaction is defined as expected if it is included in package insert or the summary of product characteristics (SPC).

Falsified medicinal product Any medicinal product with a false representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used.

Field safety corrective action (FSCA): It is an action taken by a MANUFACTURER to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

Field Safety Corrective Actions Guidance: A field safety corrective action (FSCA) is an action taken by a MANUFACTURER to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

Individual Case Safety Report (ICSR): This refers to the format and content for the submission of an individual report of suspected adverse reactions in relation to a medicinal product that occur in a single patient at a specific point of time
Lack of Efficacy: Unexpected failure of a medicine to produce the intended effect as determined by previous scientific investigation.

Medication error An unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.

Medical device: Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of following specific medical purposes. for one or more of the following specific medical purposes:
• diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
• diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
• investigation, replacement or modification of the anatomy or of a physiological or pathological process
• providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donationsand which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Misuse of a medicinal product Situations where a medicinal product is intentionally and inappropriately used not in accordance with the terms of the marketing authorisation.

National Pharmacovigilance Center: A single, governmentally recognized center (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advice on all information related to medicine safety.

Off-label use Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the terms of the marketing authorisation.

Rechallenge: The point at which a medicine is again given to a patient after its previous withdrawal. (see De-challenge)

- A positive rechallenge means:
  The same adverse reaction reappears after re-administration of the product.
- A negative rechallenge means:
  The reaction does not recur after re-administration.

Serious Adverse Event or Reaction: A serious adverse event or reaction is any untoward medical occurrence that at any dose results in:

- Death
- Islife-threatening(Note: The term “life-threatening” in the definition of “serious” refers to an AE/ADR in which the patient was at risk of death at the time of the AE/ADR; it does not refer to an AE/ADR which hypothetically might have caused death if it were more severe)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/ incapacity
- Congenital Anomaly
- Medically important event or reaction

To ensure no confusion or misunderstanding of the difference between the terms ‘serious’ and ‘severe’, The following note of clarification is provided:
The term ‘severe’ is not synonymous with serious. In the English language, ‘severe’ is used to describe the intensity (severity) of a specific reaction (as in mild, moderate or severe). However; the reaction itself may be of relatively minor medical significance (such as severe headache). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a patient's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

Severe event:
Severe reaction is a term including serious reactions but also including other severe reactions.

- Usually do not result in long-term problems.
- Could be disabling.
- Rarely life-threatening.

Side Effect: Any unintended effect of a pharmaceutical product occurring at doses normally used in humans, which is related to the pharmacological properties of the medicine. Any unintended outcome that seems to be associated with treatment, including negative or positive effects.

Signal: Information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

Spontaneous Reporting: A system whereby case reports of adverse drug reactions are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority. A spontaneous report is an unsolicited communication by a healthcare professional, or consumer to a competent authority, marketing authorisation holder or other organisation (e.g. regional pharmacovigilance centre, poison control centre) that describes one or more suspected

adverse reactions in a patient who was given one or more medicinal products. It does not derive from a study or any organised data collection systems.

Substandard products: are those that do not meet quality standards and specifications, often due to poor manufacturing practices or inadequate quality control.

Unexpected Adverse Reaction: An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the medicine if the reported AE/ADR is not included in the regional or local product labelling (e.g., Prescribing Information or Summary of Product Characteristics). In addition, an AE/ADR in an ICSR whose nature, severity, or specificity is not consistent with the term or description used in the regional or local product labelling should be considered unexpected.

1 Introduction

This Guidance for the Egyptian Pharmaceutical Vigilance System has been developed to complement and support the efforts of orienting all healthcare professionals on the important concept of Pharmacovigilance, vaccine vigilance and medical device safety.

It gives an overview of what pharmaceutical vigilance is, how to detect and classify Adverse Reaction. It also describes the reporting system to the Egyptian Pharmaceutical Vigilance Center.

The reporting requirements stated in this guideline are based mainly on the international guidelines including, International Conference for Harmonization (ICH) and the European Medicine Agency (EMA).

2 Scope

Its ultimate goal is to enhance efforts in ensuring that safe, efficacious, and quality pharmaceutical products and medical devices are made available for all Egyptians. All healthcare professionals are encouraged to actively participate in pharmaceutical vigilance and to report all suspected adverse reactions to help safeguard the population's health.

3. What is Pharmacovigilance?

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

This term is expanded to include other pharmaceutical products and medical devices as well.

- Adverse drug reaction (ADR) Vs.AdverseEvents (AE)

According to ICH-E2A (refer to GVP Annex IV), the definition of an adverse reaction requires at least a reasonable possibility of a causal relationship between the suspected medicinal product and the adverse event. Unlike an adverse event, an adverse reaction is characterized by the suspicion of a causal association between the medicinal product and the occurrence.

3.1 Importance of Pharmacovigilance

The information about pharmaceutical products collected during the pre-marketing phase is incomplete with regard to adverse drug reactions and this is mainly because:

- Patients enrolled in clinical trials are limited in number and are not representative to the public at large.
- In addition, the conditions of use of medicines differ from those in clinical practice and the duration is limited.
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete.

❖ Therefore, monitoring the pharmaceutical products in the post marketing settings is important to permit detection of less common but sometimes very serious ADRs. Therefore, healthcare professionals worldwide should report on Adverse Reaction as it can save the lives of their patients and others.

3.2 Objectives of Pharmacovigilance

✓ To improve patient care and safety in relation to the use of pharmaceutical products.
✓ To improve public health and safety in relation to the use of pharmaceutical products.
✓ To detect problems related to the use of pharmaceutical products and communicate the findings in a timely manner.
✓ To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit.

- ✓ To encourage the safe, rational and more effective (including cost-effective) use of medicines; and
- ✓ To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.

4. WHO Program for International Drug Monitoring

As a mean of pooling existing data on ADRs, WHO's Program for International Drug Monitoring (PIDM) was started in 1968. Initially a pilot project in 10 countries with established national reporting systems for ADRs, the network has since expanded significantly as more countries worldwide developed national Pharmacovigilance centers for the recording of ADRs. Currently, many countries participate in the program, which is coordinated by WHO together with its collaborating center in Uppsala, Sweden (UMC). The collaborating center is responsible for maintaining the global ADR database, VigiBase.

The WHO Collaborating Center analyses the reports in the database to:

1. Identify early warning signals of serious adverse reactions to medicines
2. Evaluate the hazard
3. Undertake research into the mechanisms of action to aid the development of safer and more effective medicines

Through an advisory committee, WHO plays an important role in the provision of expert advice on all matters relating to the safety of pharmaceutical products. The Committee also exists to facilitate consistent policies and action among member countries and to advise those who may be concerned about action taken in another country.

Egypt has been a full member within the Program for International Drug Monitoring since 2001, allowing the communication with vigilance centers globally and the access to safety information gathered globally, and sharing the collected Egyptian data with the Global database.

5. Introduction to the Egyptian Pharmacovigilance system

The Pharmaceutical Vigilance General Administration (PVGA), also known as Egyptian Pharmaceutical Vigilance Center has been established in December 2009 within the Egyptian Drug Authority (EDA), in line with the global trend to strengthen the rules governing pharmacovigilance. It is the national center in Egypt responsible for monitoring the safety of pharmaceutical products throughout its life cycle. It also represents the regulatory body for pharmaceutical companies for subjects related to the field of pharmaceutical vigilance. Regional centers and collaborating centers were established in order to spread the awareness of pharmacovigilance and collect safety information from all governorates of Egypt.

In order perform its role, EPVC collects all safety information that falls within the safety scope including "Adverse events, lack of efficacy, drug interactions, overdoses, misuse, medication errors, off-label use and problems resulting from the use of substandard or falsified medicines quality problems and medical device incidence reports"

6. Types of ADRs

Type A

Augmented pharmacologic effects - dose dependent and predictable (medicine actions) are those which are due to (exaggerated) pharmacological effects. Type A effects tend to be fairly common, dose related (i.e. more frequent or severe with higher doses) and may often be avoided by using doses which are appropriate to the individual patient. Such effects can usually be reproduced and studied experimentally and are often already identified before marketing.

Type B

Bizarre effects (or idiosyncratic)-dose independent and unpredictable (Patient reactions) characteristically occur in only a minority of patients and display little or no dose relationship. They are generally rare and unpredictable, and may be serious and are notoriously difficult to study. Type B effects are either immunological or non- immunological and occur only in patients, with - often unknown -predisposing conditions. Immunological reactions may range from rashes, anaphylaxis, vasculitis, inflammatory organ injury, to highly specific autoimmune syndromes. Also, non-immunological Type B effects occur in a minority of predisposed, intolerant, patients, e.g. because of an inborn error of metabolism or acquired deficiency in a certain enzyme, resulting in an abnormal metabolic pathway or accumulation of a toxic metabolite. Examples are chloramphenicol aplastic anemia and isoniazid hepatitis.

Type C

Chronic effects refer to situations where- often for unknown reasons- the use of a medicine increases the frequency of a "spontaneous" disease. Type C effects maybe both serious and common (and include malignant tumors) and may have pronounced effects on public health. Type C effects may be coincidental and often concern long term effects; there is often no suggestive time relationship and the connection may be very difficult to prove.

Type D

Delayed effects, example is tardive dyskinesia after decades of using typical antipsychotics.

Type E

End-of-treatment effects refer to the undesired effects of ceasing the drug (withdrawal reactions). Example: opiate withdrawal.

Type F

Failure of therapy.

7. Seriousness of Adverse drug reactions

A serious adverse event or reaction is any untoward medical occurrence associated with the use of a medical product in a patient that at any dose, the patient outcome is one of the following:

- *Death: Report if the patient's death is suspected as being a direct outcome of the adverse reaction*
- *Life-Threatening: Report if the patient was at substantial risk of dying at the time of the adverse reaction or it is suspected that the use or continued use of the product would result in patient's death.*

> ***NOTE***
>
> *The term "life-threatening" in the definition of "serious". The term "life-threatening" in the definition of "serious" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe.*

- *Hospitalization (initial or prolonged): Report if admission to the hospital or prolongation of a hospital stay results because of the suspected adverse reaction.*

> ***NOTE***
>
> *"Hospitalization" refers to inpatient hospitalization that includes initial admission to the hospital on an inpatient basis.*
>
> *An emergency room visit, examination or treatment delivered as an outpatient - which does not result in admission to the hospital - does not qualify for this outcome, but it should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event)*

- *Disability: Report if the adverse reaction resulted in a significant, persistent, or permanent disability/incapacity; (change, impairment, damage, or disruption in the patient's body function/structure, physical activities, or quality of life).*
- *Congenital Anomaly: Report if there are suspicions that exposure to a medical product in one of the parents prior to conception or during pregnancy resulted in an adverse outcome in the child (birth defect).*
- *Medically important event or reaction: Medical and scientific judgment should be exercised in deciding whether other situations should be considered serious such as important medical events that might NOT*

be immediately life-threatening or result in death or hospitalization but might cause danger to the patient or might require intervention to prevent one of the other outcomes listed in the definition above.

Examples:

- Breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.
- Acetaminophen overdose that could induce hepatotoxicity and require treatment with acetylcysteine to prevent permanent damage. Burns from radiation equipment requiring medicine therapy
- Any suspected transmission via a medicinal product of an infectious agent is also considered a serious adverse reaction.
- Intensive treatment in an emergency room or at home for allergic bronchospasm,
- Convulsions that do not result in hospitalization,
- Development of medicine dependency or medicine abuse

The Spontaneous reporting structure is the voluntary and the most common way through which the regulatory bodies collect safety information for pharmaceutical products and medical devices once they are on the market.

The pharmaceutical product reporting form-Yellow Card-(Annex I,II) issued by Egyptian pharmaceutical vigilance center to collect information on medicinal products' ADRs from healthcare professionals and members of the public. Each yellow card concerns an individual case experienced ADRs. There is a special consideration concerning the reporting for vaccines clarified in appendix I.

The Medical Devices Incident User Report Form (Pink Card) (Annex IV, V) is used by PVGA to collect information on Medical Devices' incidents from healthcare professionals and members of the public. The Medical Devices Vigilance System is clarified in (Appendix II).

8. Who, what, and how to report?

8.1 Who should report?

8.1.1 Healthcare Professionals are the preferred source of information in pharmaceutical vigilance. This includes:

- Physicians-who prescribe the pharmaceutical products and follow up with the patients.
- Family practitioners, medical specialists, and dentists.
- Nurses and other health workers who may administer medicines and should report relevant adverse drug reactions experienced by their patients.

8.1.2 Pharmacists who can play an important role in the stimulation of reporting and in the provision of additional information (for example, on co-medication and previous
Medicine use).

8.1.3 Patients and their relatives: They can also report their experienced adverse drug reactions directly to

PVGA, or through their healthcare professionals. In this case the patient's permission is sought to contact their healthcare professionals for additional information and data verification.

8.1.4 Marketing authorization holder (MAH): As being responsible for the safety of their products, are obligated to report serious adverse drug reactions they receive about their products to PVGA.

- Importers, exporters and distributers should report directly to the MAHs within the timelines specified in the safety exchange agreement (in accordance to the good pharmacovigilance practices guidelines for MAHs).

➢ Minimum Criteria for a valid report

At least four essential data elements must be available for a report to be considered valid, entered into the national ADR database, and used for signal detection activities. If one or more of these elements are missing, follow-up should be conducted to obtain the required information, validate the report, and complete its processing, as follow:

One identifiable patient	**An identifiable reporter**
At least 1 of the following information about the patient should be reported: I. Patient initials II. Sex III. Age at time of reaction or date of birth or age group	1.Name It is also preferable to report the following I. Contact details II. Qualification (if healthcare professional) III. Address
Suspected pharmaceutical product (s) (Generic name and/or brand name)	**Suspected adverse reaction(s)** (Description of the reaction)

Valid Report

➢ *Characteristics of good case report*

The quality of the reports is critical for appropriate evaluation of the relationship between the product and adverse reaction; thus, a good case report includes the following elements:

- Description of the adverse reaction, including time to onset of signs or symptoms and the seriousness of the reaction/s; date the reaction stopped, clinical course of the reaction and patient outcome with relevant investigation results (if available)
- Suspected and concomitant medicines details (i.e., Name, strength, dose, frequency, dosage form, route of

administration, indication for use, duration of use and batch number especially for vaccines and other biological products), including over-the-counter medications, dietary supplements, and recently discontinued medications;

- Patient characteristics, including the initials, age, sex, weight, and baseline medical condition prior to product therapy, co-morbid conditions, relevant family history of disease, and presence of other risk factors;
- Documentation of the diagnosis of the reactions, including methods used to make the diagnosis;
- Clinical course of the reaction and patient outcomes (e.g., hospitalization or death);
- Relevant therapeutic measures and laboratory data at baseline, during therapy, and subsequent to therapy, including blood levels, as appropriate;
- Information on de-challenge and re-challenge.
- Any other relevant information (e.g., other details relating to the reaction or information on benefits received by the patient, if important to the assessment of the reaction).

8.2 What should be reported?

Any suspected adverse reaction that a patient has experienced should be reported, especially the following:

- ***Medicines under additional monitoring****:* When new drugs and vaccines are first marketed, they are intensively monitored in order to confirm the risk/benefit profile of the product. Such products are labelled with an inverted black triangle▼, and healthcare professionals are encouraged to report **all** suspected ADRs which occur as a result of the use of all black triangle drugs regardless of the seriousness of the reaction.

- Also, black triangle status may be re-assigned to an established product if it is granted a new indication or route of administration, if it is marketed as a new combination with another established active ingredient, or if it is targeted towards a new patient population.

- For established medicines or well-known medicines report all serious or unusual unexpected suspected adverse reactions whether it is considered serious or non-serious adverse reactions.

- Report if an increased frequency of a given reaction is suspected.

- Report all suspected ADRs associated with drug-drug, drug food or drug-food supplements (including herbal and complementary products) interactions.
- Report ADRs in special fields of interest such as:
  - ADRs occurring from overdose or medication error.
  - Medicine abuse and misuse.
  - Medicine use in pregnancy (including teratogenicity) and during lactation.
  - In children under the age of 18, all suspected ADRs occurring should be reported regardless of whether the medicine is licensed for use in children. Children are often not exposed to medicines during clinical trials and many medicines are used in children even if they are not licensed for this purpose. This means that monitoring of medicine safety is particularly important for this age group.
  - ADRs in geriatrics, since they are more likely to experience them as a result of age-related increases in the frequency of drug use, sensitivity to drug effects, and prevalence of predisposing conditions. In the frequency of drug use, sensitivity to drug effects, and prevalence of predisposing conditions.
  - ADRs in patients with impaired kidney or liver function, ADRs are more frequent among them because of alteration in their pharmacokinetics and pharmacodynamics parameters and multiple comorbidities.

8.3 How to report?

Refer to section 11 (How to submit ADR report?)

8.4 How to recognize ADRs in patients?

ADRs are difficult and sometimes impossible to distinguish from the disease being treated since they may act through the same physiological and pathological pathways. However, the following approach is helpful in assessing possible drug-related ADRs:

- Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised.
- Take a proper history and do a proper examination of patient
- ✓ A full medicine and medical history should be taken
- ✓ An ADR should be your first differential diagnosis at all times
- ✓ Ask if this adverse reaction can be explained by any other cause e.g. Patient's underlying disease, other medicines including over-the-counter medicines or traditional medicines, toxins or foods
- ✓ It isessentialthatthepatientisthoroughlyinvestigatedtodecidewhattheactualcauseof any new medical problem is.
- ✓ A medicine-related cause must be considered, especially when other causes do not explain the patient's condition
- following the medicine administration?
- Some reactions occur immediately after the medicine has been given while others take time to develop. The time from start of therapy to the time of onset of the suspected reaction must be logical.
- Carry out a thorough physical examination with appropriate laboratory investigations if necessary. Try to describe the reaction as clearly as possible - where possible, provide an accurate diagnosis.
- Effect of de-challenge and re-challenge should be determined.
- Check the known pharmacology of the medicine.
- Check if the reaction is known to occur with the particular suspected medicine as stated in the package insert or other reference.
- ✓ Remember: if the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular suspected *medicine.*

8.5 What are the benefits of these reports for the patients and the health care providers?

The reporting by the healthcare provider and patient is completely voluntarily, they will stand to benefit:

- Improvement on the quality of care offered to patients
- Reduction of medicine related problems leading to better treatment outcome
- Improved patient confidence in professional practice, hence professional growth
- Access to feedback information on medicine related problems reported within the country and international
- Improved knowledge
- Satisfaction for the fulfillment of a moral and professional obligation

8.6 Will reporting have any negative consequences on the reporter?

- The adverse drug reaction report does not constitute an admission that the reporter or any other health professional or the medicine contributed to or caused the reaction in any way.
- The identities of the reporter, any other healthcare professionals mentioned in the report, and the patient will be kept confidential, and all identifying information will be removed before any details related to a specific adverse drug reaction are used or shared with others.
- The information obtained from the report will not be used for commercial purposes. It is only meant to improve our understanding and safe use of medicines in Egypt.

8.7 Remember: The Basic principles of efficient reporting

- ***In-time reporting***

✓ Report the suspected adverse drug reaction **as soon as it occurs**. It is recommended to report serious reports within 15 days and the non-serious reports within 90 days.

✓ Send the report quickly to the Egyptian Pharmacovigilance Center.

- ***Suspicion:***

✓ Continue your suspicion of the medicine-induced illness in the same patient and in other patients.
✓ You don't have to be sure to report.
✓ Be vigilant for signs and symptoms that indicate adverse reactions

- ***Follow-up***

✓ Follow up the patient (if possible) to know the reaction(s) outcome and document it with any new available supplementary information to submit them to the Egyptian Pharmaceutical Vigilance Center as a "Follow-up" report

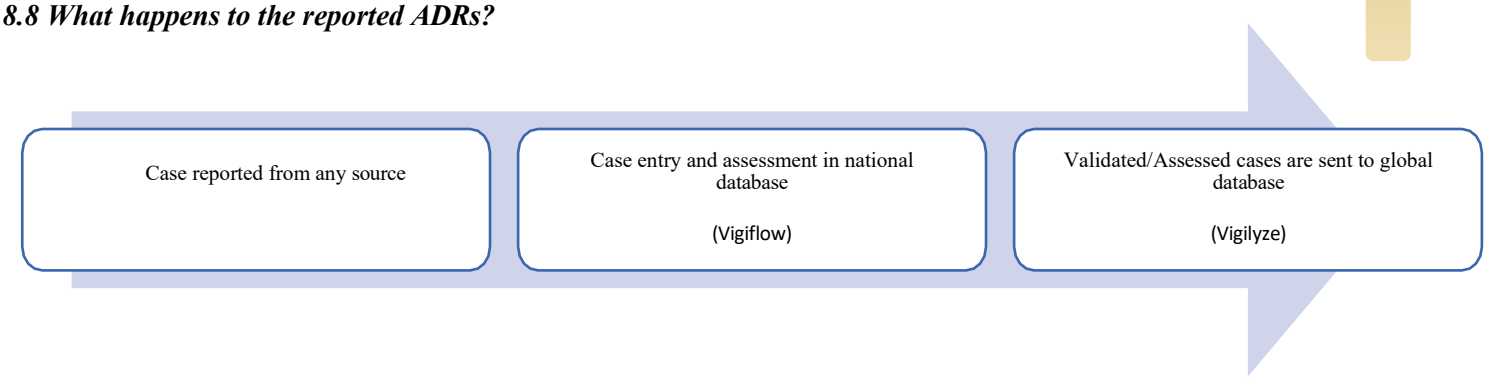
✓ When submitting a "Follow – up" report, clearly state that it is "follow- up report" and include enough details to allow accurate linking it to the originally submitted report (especially patient's identifiers such as initials, age, weight and patient's file number)

- *Accuracy and completeness*

✓ Ensure that each reported suspected adverse reaction is accurate with all the necessary information, as much as is available to you. This is very important for accurate causality assessment of the medicine to have caused that reaction.

✓ Remember the 4 basic components that make a report valid are: One identifiable patient
i. Identifiable reporter
ii. One or more adverse reaction or product problem
iii. One or more pharmaceutical product(suspected)
If the above information is missing, the report will not be valid
✓ Remember to fill in all information accurately and in clear legible writing

8.8 What happens to the reported ADRs?



- A healthcare professional or a marketing authorization holder reports a suspected adverse drug reaction related to one or more pharmaceutical products to PVGA. Reports are made in writing (e.g. using reporting forms) or electronically via the e-reporting link.
- Reports are collected, collated, validated and assessed (causality assessment clarified below) by the pharmacovigilance center then entered into the national database. Serious and unexpected reactions are handled with the highest priority. The details of the report stored in the national database are submitted to the global database (monitored by Uppsala Monitoring Centre (UMC)) for more analysis.
- The information compiled in the national database is used to identify potential signals, clarify risk factors and apparent changes in reporting profiles and to promote safe use of medicines at the local, national and international levels.
- A suitable action may be recommended accordingly, such as:
  - Requesting Additional investigations into the use of a pharmaceutical product
  - Appropriate changes in the package insert
  - Enhancing educational initiatives to improve the safe use of pharmaceutical products
  - Other regulatory and health promotion interventions as the situation may warrant including withdrawal/ recall.

The ultimate purpose of ADR reporting and monitoring is to reduce risks associated with drug prescribing and administration and improve patient care, safety and treatment outcome

9. Causality assessment

Causality is the relationship between two events (the cause and the effect), where the second event is a consequence of the first.

Causality assessment is the method by which the extent of relationship between a medicine and a suspected reaction is established, i.e., to attribute clinical events to medicines in individual patients or in case reports.

PVGA adopts the UMC Causality Categories

Term	***Description***
Certain	A clinical reaction, including laboratory test abnormality, occurring in a plausible time relationship to medicine administration, and which Cannot be explained by concurrent disease or other medicines or chemicals. The response to withdrawal of the medicine (dechallenge) should be clinically plausible. The reaction must be definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon). Using a satisfactory rechallenge procedure if necessary.
Probable/ Likely	A clinical reaction, including laboratory test abnormality, with A reasonable time sequence to administration of the medicine, Unlikely to be attributed to concurrent disease or other medicines or chemicals, and which Follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.
Possible	A clinical reaction, including laboratory test abnormality, with A reasonable time sequence to administration of the medicine, but which could also be explained by concurrent disease or other medicines or chemicals. Information on medicine withdrawal may be lacking or unclear.
Unlikely	A clinical reaction, including laboratory test abnormality, with a temporal relationship to medicine administration which makes a causal relationship improbable, and other medicines, chemicals or underlying disease provide plausible explanations.
Conditional/ Unclassified	Event or laboratory test abnormality ▪ More data for proper assessment needed, or ▪ Additional data under examination

Unassessable/ Unclassified	Report suggesting an adverse reaction ▪ Cannot be judged because information is insufficient or contradictory ▪ Data cannot be supplemented or verified

10. MEDICAL DEVICES VIGILANCE SYSTEM

- It is critically important that the safety and performance of medical devices are continually assessed when they are in use i.e. post-marketing, as the information collected during the pre-marketing phase is incomplete with regard to adverse incidents and this is mainly because:
- Data available in the pre-marketing review process cannot predict all possible device failures or incidents arising from device misuse in the Post-Marketing phase.
- It is through actual use that unforeseen problems related to safety and performance can occur.
- Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability.
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
- The following products shall also be deemed to be medical devices:
- Devices for the control or support of conception;
- Products specifically intended for the cleaning, disinfection or sterilization of device.

Classification of Medical Devices:

Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices, their inherent risks, the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device

- The Medical Device Vigilance System was set up under the medical device regulations to minimize risks to the safety of patients, users and others.
- Medical device safety issues can be identified through manufacturer or health professional (user) reporting, through identification and reporting of issues by members of the public or through information sharing with other competent authorities
- Objectives of the Vigilance System are:

1. To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse incident.
2. To enable the competent authorities to monitor the effectiveness of the Manufacturers' follow-up on reported incidents.
3. To facilitate a direct and early implementation of Field Safety Corrective Actions (FSCA).

4. To enable the health-care professionals and users who are responsible for the maintenance and the safety of medical devices to take the necessary steps once the corrective (or other) action is identified.
5. Competent authorities may also monitor experience with devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers

- The Medical device vigilance system achieves its objectives in several ways:
- Through manufacturers and users submitting vigilance reports to the relevant competent authorities (The Egyptian Drug Authority - EDA).
- Through the evaluation of reported incidents by the competent authorities.
- Through the dissemination of information, which may be used to prevent recurrence of the incident, or to alleviate the consequences of such incidents, in cases when it is necessary to do so.
- Vigilance issues can be related to an adverse incident or to a field safety corrective action.
- Responsibilities of the Users
  - USERs are encouraged to have an active role in the Vigilance System. Furthermore, for the successful operation of the vigilance system to be established, their involvement is vital. It is through the users that:
  - Suspected incidents are made known to the manufacturers, and
  - With their close involvement and co-operation that the implementation of FSCAs is made possible.
  - The involvement of users is promoted and encouraged through the relationship the manufacturer develops with his customer (the user). This user involvement may also be reinforced by separate advice from Medical Device Safety Unit (MDSU).

10.1 Reporting Guidance

An adverse incident is an event during use of the device which might lead to or might have led to death of a patient, or user or of other persons or to a serious deterioration in their state of health should be reported to the MDSU/EDA.

10.1.1 What to Report

USERs or those given specific responsibility for reporting incidents that have occurred with medical devices should report incidents that meet the criteria within this guideline to the manufacturer and/or to MDSU.

10.1.2 Who Should Report

The MDSU/EDA strongly encourages those who have experienced a safety issue with a medical device to report that issue to us. A voluntary reporting system is currently operated for users of medical devices, healthcare professionals or any other person who identifies a medical device safety issue.

10.1.3 When to Report

USERs are encouraged to report all adverse incidents as soon as possible. Serious cases ought to be reported by the fastest means possible. Initial incident reports should contain as much relevant detail (e.g. Medical Device name, type, model…etc.) as is immediately available, but reporting ought not to be delayed for the sake of gathering additional information.

10.1.4 How to Report

The USERs are encouraged to use the" USER Reporting Form- The Pink Card" in accordance with this guidance and to provide contact details when reporting to the manufacturer or MDSU. (Annex III)

10.1.5 What to Do with the Device

- All items, together with relevant packaging materials, ought to be quarantined; they ought not to be repaired, or discarded.
- The device should be returned to the manufacturer in accordance with their instructions unless otherwise required by MDSU or other legal requirements.
- USERs ought to contact the manufacturer to obtain information relating to the procedure for returning the suspect device. The device should be appropriately decontaminated, securely packaged, and clearly labelled, including the CA (Registration No.) or manufacturer reference number if needed.
- Medical devices ought not to be sent to MDSU unless it has been specifically requested.

10.1.6 Further Local Information

- Reporters are encouraged to cooperate with the manufacturer and MDSU by providing further information
- Concerning incidents which should become available e.g. relevant outcomes of internal investigations.
- Concerning the device or patient outcomes e.g. subsequent death.

10.2 Field Safety Corrective Actions Guidance

- A field safety corrective action (FSCA) is an action taken by a MANUFACTURER to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a Field Safety Notice (FSN). The Field Safety Corrective Actions (FSCA) may include, for example:
- The repair/replace/return of a medical device to the supplier;
- Device modification/adjustment/relabeling;
- Advice given by manufacturer regarding the use of the device and/or the follow-up (monitoring) of patients, users or others.

10.2.1 Importance of Field Safety Notices (FSNs)

- Field Safety Notices are an important means of communicating safety information to medical device users in all healthcare areas. Field Safety Notices may also be used to provide updated information and request feedback.
- It is therefore important that users are encouraged to develop effective closed loop systems that ensure the dissemination of the Field Safety Notices and the timely completion of the actions outlined.

10.2.2 Distribution

Healthcare organizations should be encouraged to help ensure that the FSN reaches all in the organization that needs to be aware and/or take the recommended action.

10.2.3 Action

USERs responsible for the maintenance and the safety of medical devices are encouraged to take the actions advised in the manufacturer's Field Safety Notice. These actions ought to be taken in co-operation with the manufacturer where required. They may also include associated actions recommended by MDSU and/or inspection department in connection with the FSCA, including providing any requested feedback.

10.2.4 Access to Devices

USERs are responsible for the maintenance and the safety of medical devices are encouraged to:

a. Facilitate manufacturer access to the device if this is required, and

b. Work with the manufacturer when needing to balance the individual risks and benefits for any dependent patients using affected device.

11. How to submit ADR report?

I: For medicine and medical devices

- **By using electronic reporting (e-reporting) on the Website:**

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

- **E-mail**

  Pv.followup@edaegypt.gov.eg

  Pv.md@edaegypt.gov.eg

- **Hotline**

  15301

- **Hand by hand**

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

- **QR code for E-reporting**

II: For Vaccines

Refer to the Egyptian Guideline on surveillance of Adverse Events Following Immunization (AEFI) using the following link:

Egyptian Guideline on surveillance of Adverse Events Following Immunization (AEFI)

12. Annexes:

Annex I: English yellow card

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A. of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
إ.ع. اليقظة الصيدلية

Adverse Drug Reactions Reporting Form

- *If you suspect that an adverse reaction may be related to a certain drug or a combination of drugs, you should complete this form and send it to the address shown at the end of the card*
- *Please report all serious and adverse reactions.*

A – Patient Details

Patient initials: ---------- Sex: □ Male □ Female Weight: -------kg Age/age group: --------
(Optional)

B – Suspected Drug(s)

Drug Name *(Generic & trade)*	Concentration	Used for	Dose	Route	Date started	Date stopped	Batch number

C – Suspected Reaction(s)

- Please describe the reaction(s): ----------
- Date reaction(s) started: ---------- Date reactions(s) stopped: ----------
- Did the Reaction Stop after stopping the drug? □ Yes □ No □ Don't Know
- Did the Reaction Reappear after retaking the drug? □Yes □ No □ Don't Know □ Did not retake the drug
- Patient Condition (Outcome): □Recovered □ Not recovered □Recovering □ Recovered with sequelae □ Fatal
- Was the reaction serious (based on the reasons below)? □ Yes □ No □ Don't Know

If yes (serious), specify one ormore:
□Patient Died □Life threatening □ Hospitalization
□ Prolonged Hospitalization □ Congenital Anomaly □ Permanent Disability
□ Required intervention to prevent Damage □ Other, specify ----------

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A. of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
إ.ع. اليقظة الصيدلية

D – List of other drugs taken (Please list any other drugs taken while (concurrently) administered *other than the suspected drug/s*)

Drug Name (Generic & trade)	Concentration	Used for	Dose	Route	Date started	Date stopped	Batch number

E – Reporter Details

The One who fill in this form: ◻ Patient ◻Physician ◻Pharmacist ◻ Nurse ◻ Other, specify_____

Name: ---------- Specialty *(if physician)*: ----------

Professional address (institution/ clinic): ----------

e-mail: ---------- Telephone/ mobile :----------

Date of reporting: ----------

F- Any More Comments (Medical history "eg: chronic diseases", other diseases, allergies):

- *The information in this report is confidential and totally protected including both the Patient and Reporter identity.*
- *Contact details required to complete the case information if necessary.*
- *You can send voluntarily the Adverse Drug Reactions (ADRs) Reports to the Egyptian Pharmaceutical Vigilance Center as per the contact details below.*
- *Reporting for ADRs is Vital for Safely usage of drugs. Enough information will help the Center to evaluate the Safety of the Drugs marketed in our Country.*

Head quarter: Egyptian Pharmaceutical Vigilance Center (EPVC)- Egyptian Drug Authority (EDA)
21 Abd Elaziz Al Souad st. – Marsial El-Roda – Cairo,
Tel: (+2)02 25354100
Extension (Tel):1333 **Extension (tel):** 1470
Hotline:15301
Website: www.edaegypt.gov.eg
E-mail: pv.followup@edaegypt.gov.eg

Alexandria Regional Center:
Egyptian National Insurance Company Building, 57 El-Horreya Road, 8th floor next to the Latin Quarter Pharmacy- Alexandria
e-mail: pv.alex@edaegypt.gov.eg

Cairo Regional Center:
e-mail: pv.cairo@edaegypt.gov.eg

Sohag Regional Center: The old building of the Health Affairs Directorate- 2nd floor- next to the security directorate building- Nasser city- Sohag
e-mail: pv.sohag@edaegypt.gov.eg

Annex II: Arabic yellow card

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A. of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
إ.ع. اليقظة الصيدلية

نموذج الإبلاغ عن الآثار العكسية للأدوية

- *في حالة حدوث أى آثار عكسية عند تناولك دواء معين أو مجموعة من الأدوية، فعليك باستيفاء هذا التقرير وإرساله إلى العنوان المبين فى أسفل النموذج.*
- *من فضلك سجل جميع الآثار العكسية سواء كانت عادية أو خطيرة.*

آ - بيانات المريض

الحروف الأولى من اسم المريض: _____ النوع: □ ذكر □ أنثى الوزن: ____كجم العمر /الفئة العمرية:.....
(اختياري)

ب - الأدوية المشتبه بها

اسم المستحضر (التجاري والعلمي)	التركيز	يستخدم لعلاج	الجرعة	طريقة الاستخدام	تاريخ بدء الاستخدام	تاريخ وقف الاستخدام	رقم التشغيلة

ج - الآثار العكسية المشتبه بها

- من فضلك صف الأثر العكسي الذي ظهر :_____
- تاريخ بدء الأثـر العكسي: ---------- تاريخ إنتهاء الأثـر العكسي : _____
- هل توقف الأثر بعد وقف استخدام المستحضر؟ : □ نعم □ لا □ لا أعرف
- هل ظهر الأثر بعد إعادة استخدام المستحضر؟ : □ نعم □ لا □ لا أعرف □ لم يتم إعادة الاستخدام
- حالة المريض الآن: □ تعافي □ مازال الأثر العكسي مستمر □ مازال يتعافى □ تعافى مع وجود مضاعفات
- هل كان الأثر العكسي خطيراً (وفقا لأسباب الخطورة المذكورة أدناه) ؟: □ نعم □ لا □ لا أعرف

إذا كانت الإجابة بنعم (الأثر خطير) حدد سبب أو أكثر:

□ تسبب في الوفاة □ مهدد للحياة □ تسبب في دخول المريض المستشفى
□ تسبب في إطالة مدة البقاء في المستشفى □ تسبب في عيوب خلقية للأجنة □ تسبب في إعاقة دائمة
□ تطلب تدخل طبي أو جراحي لمنع حدوث إعاقة أو تلف دائم □ أخرى (حدد):_____

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A. of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
إ.ع. اليقظة الصيدلية

د - بيانات عن الأدوية الأخرى المتناولة (اذكر الأدوية الأخرى التي تم تناولها أثناء (تزامناً مع) تناول المستحضر موضع الشكوى)

اسم المستحضر (التجاري والعلمي)	التركيز	يستخدم لعلاج	الجرعة	طريقة الاستخدام	تاريخ بدء العلاج	تاريخ وقف العلاج	رقم التشغيلة

هـ - بيانات عن مقدم التقرير

الذي قام باستيفاء التقرير: ☐ المريض ☐ الطبيب ☐ الصيدلي ☐ التمريض ☐ أخرى (حدد):_____

الاسم: _____ التخصص (للطبيب):_____

عنوان العمل (لمقدمي الرعاية الصحية): _____

التليفون/محمول:_____ البريد الإلكتروني: _____

التاريخ: _____

و - أي تعليقات اخرى: (التاريخ الطبي «مثل الأمراض مزمنة»، أمراض أخرى يعاني منها المريض، حساسية ،.....)

- *يتم التعامل مع المعلومات الواردة في التقرير بسرية تامة وهي محمية بشكل كامل بما في ذلك هوية المريض ومعد التقرير.*
- *بيانات الاتصال مطلوبة لاستكمال معلومات الحالة المقدمة اذا دعت الحالة لذلك.*
- *تستطيع إرسال تقارير الآثار العكسية لمركز اليقظة الصيدلية المصري بشكل تطوعي وفقا لمعلومات الاتصال الموضحة أدناه.*
- *إن الإبلاغ عن الآثار العكسية أمر حيوي وهام لتحقيق الأستخدام الآمن للدواء. كما أن المعلومات الكافية المقدمة من قبل المرضى تمكن المركز من تقدير مدى مأمونية*

المركز الرئيسي: إدارة اليقظة الدوائية - مركز اليقظة الصيدلية المصري – هيئة الدواء المصرية
21 ش عبد العزيز آل سعود – المنيل الروضة – القاهرة
تليفون:25354100 02(+2)
داخلي(ت): 1333 **داخلي (2):** 1470
الخط الساخن: 15301
موقع إلكتروني: www.edaegypt.gov.eg
بريد إلكتروني: pv.followup@edaegypt.gov.eg
رابط الإبلاغ الإلكتروني: عن طريق QR Code

- **المركز الفرعي بالإسكندرية:** مقر هيئة الدواء بالإسكندرية 57 (ش فؤاد) طريق الحرية - الاسكندرية
  بريد إلكتروني: pv.alex@edaegypt.gov.eg
- **المركز الفرعي بالقاهرة:**
  بريد إلكتروني: pv.cairo@edaegypt.gov.eg
- **المركز الفرعي بسوهاج:** مديرية الشئون الصحية – المبنى القديم الدور الثاني- بجوار مديرية الأمن –مدينة ناصر – سوهاج
  بريد إلكتروني: pv.sohag@edaegypt.gov.eg

Annex III: English pink card

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة للرقابة الصيدلية

Medical Device Incident User Report Form

I. Patient Information			
Name/Initials:	Sex: □ Male □ Female	Weight: KG	Age:
II. Medical Device Information			
Name of Medial Device:		Type of Medical Device (e.g. Pacemaker):	
Manufacture Date:		Expiry Date:	
Reference/Registration No.:		Code/Model No.:	
Catalogue No.:	Lot/Batch No.:	Serial No.:	
Manufacturer Name: Address: Phone:		Supplier Name: Address: Phone:	
Quantity Defective (Number):		Current Location:	
Has the manufacturer/supplier been contacted? □ Yes □ No (Keep the device till be requested by the supplier - Please Do Not Discard the device or related consumables & packaging - Do not send medical devices to MDSD/EDA unless you have been specifically requested to do so)			
III. Incident Information			
Incident Description/Nature of Device Defect (includes any action by patient, carer or healthcare professional, or by the manufacturer or supplier):			
Action Taken:			
Type of Injury: □ Death □ Serious □ Non-serious □ None		Date of Incident:	

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
إ.ع اليقظة الصيدلية

Medical Device Incident User Report Form

IV.Reporter Information (Will Be Kept Confidential)	
Reporter's Name:	Position/Occupation:
Organization:	Address:
Phone/Mobile No.:	Email:
V. Other Comments:	

Head quarter: Egyptian Pharmaceutical Vigilance Center (EPVC)- Egyptian Drug Authority (EDA) 21 Abd Elaziz Al Souad st. – Manial El-Roda – Cairo, **Tel:** (+2)02 25354100 **Extension (Tel):**1333 **Extension (tel):** 1470 **Hotline:**15301 **Website:** www.edaegypt.gov.eg **E-mail:** pv.followup@edaegypt.gov.eg	**Alexandria Regional Center:** Egyptian National Insurance Company Building, 57 El-Horreya Road, 8th floor next to the Latin Quarter Pharmacy- Alexandria e-mail: pv.alex@edaegypt.gov.eg **Cairo Regional Center:** e-mail: pv.cairo@edaegypt.gov.eg **Sohag Regional Center:** The old building of the Health Affairs Directorate- 2nd floor- next to the security directorate building- Nasser city- Sohag e-mail: pv.sohag@edaegypt.gov.eg

Annex IV: Arabic pink card

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
ج.ع البقظة الصيدلية

نموذج المستخدم للإبلاغ عن حادث خاص بمستلزم طبى

1. بيانات المريض			
الاسم/الأحرف الأولى:	النوع: □ ذكر □ أنثى	الوزن: كجم	السن:
2. بيانات المستلزم الطبى			
اسم المستلزم الطبى:	نوع المستلزم الطبى (مثلاً: منظم ضربات قلب):		
تاريخ التصنيع:	تاريخ انتهاء الصلاحية:		
الرقم المرجعى/رقم التسجيل:	رقم الكود/الموديل:		
رقم الكتالوج:	رقم اللوط/الباتش:	رقم المسلسل:	
اسم الصانع: العنوان: الهاتف:	اسم المورد: العنوان: الهاتف:		
الكمية المتأثرة (رقم):	الموقع الحالى:		
هل تم التواصل مع الصانع/المورد؟ □ نعم □ لا (يرجاء الاحتفاظ بالمستلزم لحين تسليمه للمورد عند الطلب - لا تقم بالتخلص من المستلزم أو ملحقاته أو الغلاف الخاص به - لا تقم بإرسال المستلزم لإدارة سلامة المستلزمات الطبية/هيئة الدواء المصرية ما لم يُطلب منك ذلك لاحقًا)			
3. بيانات الحادث			
وصف الحادث/ طبيعة مشكلة المستلزم (بما فى ذلك أى إجراء من قبل المريض أو مقدم الرعاية أو أخصائى الرعاية الصحية، أو من قبل الصانع أو المورد):			
الإجراء المتخذ:			
نوع الحادث: □ وفاة □ خطير □ غير خطير □ لا يوجد	تاريخ الحادث:		

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Pharmaceutical Care
G.A of Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
ج. اليقظة الصيدلية

نموذج المستخدم للإبلاغ عن حادث خاص بمستلزم طبى

4. بيانات المبلغ	
اسم المبلغ:	المنصب/الوظيفة:
المؤسسة:	العنوان:
رقم الهاتف/المحمول:	البريد الإلكتروني:
5. تعليقات أخرى:	

المركز الرئيسي: إدارة اليقظه الدوائيه - مركز اليقظه الصيدليه المصري – هيئه الدواء المصريه
21 ش عبد العزيز آل سعود – المنتزل الروضة – القاهرة
تليفون: 25354100 02(+2)
داخلي(ت): 1333 **داخلي (2):** 1470
الخط الساخن: 15301
موقع الكتروني: www.edaegypt.gov.eg
بريد الكتروني: pv.followup@edaegypt.gov.eg

- **المركز الفرعي بالإسكندرية:** مقر هيئة الدواء بالإسكندرية 57 (ش فؤاد) طريق الحرية - الإسكندرية
  بريد الكتروني: pv.alex@edaegypt.gov.eg
- **المركز الفرعي بالقاهرة:**
  بريد إلكتروني: pv.cairo@edaegypt.gov.eg
- **المركز الفرعي بسوهاج:** مديرية الشئون الصحية – المبنى القديم الدور الثاني- بجوار مديرية الأمن -مدينة ناصر – سوهاج
  بريد إلكتروني: pv.sohag@edaegypt.gov.eg

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14. History Table

Version No.	Issue date	Summary of Changes
4	October 2024	Under when to report: Addition of the timeline of reporting serious cases **Added paragraph** Under how to submit an ADR report Refer to Egyptian Manual on surveillance of adverse events following immunization (AEFI) **Deleted** AEFI appendix 1 AEFI reporting forms Under annexes part Arabic English **References** **Deleted references:** VOLUME 9A -of The Rules Governing Medicinal Products in the European Union– Guidelines on Pharmacovigilance for Medicinal Products for Human Use, (EMEA) 2008 Good Pharmacovigilance Practice Guide, (MHRA), 2009 **Added references:** Guideline on Good Pharmacovigilance Practice (GVP) in Egypt For Pharmaceutical Products Year **2023** **References updated to the latest version:** E2D(R1) POST-APPROVAL SAFETY DATA: DEFINITIONS AND STANDARDS FOR MANAGEMENT AND REPORTING OF INDIVIDUAL CASE SAFETY REPORTS, **Feb. 2024**

5	**July 2026**	**<u>Addition of:</u>** • ICSR definition • Positive/negative de-challenge and positive/negative re-challenge definitions • Abuse of medicinal product, misuse of medicinal product, medication error, off label use, falsified medicinal product and substandard products definitions. • Reporting channels of medical devices **<u>Modification of:</u>** • Adverse drug reaction, adverse event, causality assessment definitions. • Severe event term, medical device, side effect, signal, spontaneous reporting, unexpected ADR definitions.