

**1. Product Details**

Type of product:  Drug  Biological  Dietary Supplement  Medical Device  
 Biocides  Cosmetics  Veterinary Product  Other, specify.....

Product name (Generic &amp; Brand):

Package size:

Strength:

Dosage form:

Type of container:

Registration number (if available):

Batch number:

Manufacturer:

Distributor / Vendor:

Manufacturing date:

Expiry date:

Has the manufacturer been informed?  No  Yes, date: .../...../.....**2. Type of Quality Problem** Packaging  Physical, chemical or microbial changes  Questionable stability Suspected counterfeit product  Suspected contamination  Defective components Product confusion (caused by name, labeling, design or packaging)  Labeling Problems (caused by printing errors / omissions) Other:Was the product available for evaluation?  No  Yes

Description:

Storage condition:

Does the product require refrigeration? Was the product stored according to recommendation?  In case of therapeutic failure (please provide patient's details):

Patient name or initial (Optional):

Date of birth:

Height:

Weight:

Health Institution:

Medical Record No:

Age:

Sex:  M  F**3. Reporter Details**

Name:

Specialty (If physician):

Organization:

Address:

E-mail:

Phone / Mobile:

Fax:

Signature:

Date:

## **Advice about Voluntary Reporting:**

### **❖ Report Product Quality Problems such as:**

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

### **❖ This form can be used by:**

- Physician.
- Users.
- Pharmacist.
- Dentist.
- Nurses.
- Other healthcare providers

### **❖ How to report?**

- Fill out the quality reporting form.
- Attach additional information, if needed.
- Use a separate form for each product.

### **❖ How to submit?**

- **The Egyptian Pharmaceutical Center (EPVC) - The Egyptian Drug Authority (EDA)**
  - **Mail:** Egyptian Pharmaceutical Center (EPVC), Egyptian Drug Authority (EDA), 21 Abd El Aziz Al Soud Street. El-Manial, Cairo, Egypt, PO Box: 11451
  - **Website:** [www.epvc.gov.eg](http://www.epvc.gov.eg)
  - **Telephone:** +2 02 (23648046, 23640368, 23684381, 23684288) Extension No: 1303,1311
  - **Fax:** +2 02 23684194
  - **E-Mails:**
    - \*For Drugs, Biological & Dietary supplement Vigilance Department: [pv.center@eda.mohp.gov.eg](mailto:pv.center@eda.mohp.gov.eg)
    - \*For Medical Device Safety Department: [mddsd@eda.mohp.gov.eg](mailto:mddsd@eda.mohp.gov.eg)
    - \*For Biocides Vigilance Department: [biocides.epvc@eda.mohp.gov.eg](mailto:biocides.epvc@eda.mohp.gov.eg)
- **Alexandria Regional Center:** San Stefano Family Health Center 2 El-kazino st, El-Awkaf building, San Stefano, Alexandria Tel-Fax: +2 03- 5845004 E-mail: [alex.epvc@eda.mohealth.gov.eg](mailto:alex.epvc@eda.mohealth.gov.eg)
- **Cairo Regional Center:** Al-Azhar new specialized hospital 6th district Nasr City - Cairo Tel: +2 01014300013 E-mail: [cairo.epvc@eda.mohealth.gov.eg](mailto:cairo.epvc@eda.mohealth.gov.eg)
- **Sohag Regional Center:** The old building of the Health Affairs Directorate- 2nd floor- next to the security directorate building- Nasser city- Sohag Tel: +2 01063081606 - +2 01126540893 E-mail: [sohag.epvc@eda.mohealth.gov.eg](mailto:sohag.epvc@eda.mohealth.gov.eg)

### **❖ Confidentiality**

Any information related to the identity of persons will be protected; any unsolicited information will be destroyed.