



1. Product Details			
Type of product: <input type="checkbox"/> Drug <input type="checkbox"/> Biological <input type="checkbox"/> Dietary Supplement <input type="checkbox"/> Medical Device			
<input type="checkbox"/> Biocides <input type="checkbox"/> Cosmetics <input type="checkbox"/> Veterinary Product <input type="checkbox"/> Other, specify.....			
Product name (Generic & 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? <input type="checkbox"/> No <input type="checkbox"/> Yes, date: .../.../.....			
2. Type of Quality Problem			
<input type="checkbox"/> Packaging	<input type="checkbox"/> Physical, chemical or microbial changes	<input type="checkbox"/> Questionable stability	
<input type="checkbox"/> Suspected counterfeit product	<input type="checkbox"/> Suspected contamination	<input type="checkbox"/> Defective components	
<input type="checkbox"/> Product confusion (caused by name, labeling, design or packaging)		<input type="checkbox"/> Labeling Problems (caused by printing errors / omissions)	
<input type="checkbox"/> Other:			
Was the product available for evaluation? <input type="checkbox"/> No <input type="checkbox"/> Yes			
Description:			
Storage condition: Does the product require refrigeration? Was the product stored according to recommendation?			
<input type="checkbox"/> 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: <input type="checkbox"/> M <input type="checkbox"/> 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
 - **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.mohealth.gov.eg
 - *For Medical Device Safety Department: mdsd@eda.mohealth.gov.eg
 - *For Biocides Vigilance Department: biocides.epvc@eda.mohealth.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
- **Cairo Regional Center:** Al-Azhar new specialized hospital 6th district Nasr City - Cairo Tel: +2 01014300013 E-mail: 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

❖ Confidentiality

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