Saudi Food & Drug Authority
National Pharmacovigilance and Drug Safety Center

الهيئة العامة للغذاء والدواء
المركز الوطني للتيقظ والسلامة الدوائية

Saudi Vigilance

Date received:
By:

Pharmaceutical Products Quality Reporting Form

(Form NO. PQ-1)

*Note: this form is **NOT** for reporting adverse drug reactions **(ADR)**.For ADR reporting use **form NO. ADR-1***

A. Product Details

Type of product:	☐ **Drug**	☐ **Vaccine**	☐ **Herbal**	☐ **Other, specify**
Product name (Generic & Brand):				
Package size:		**Strength:**		**Dosage form:**
Registration number (if available):			**Batch number:**	
Manufacturer:			**Distributor / Vendor:**	
Manufacturing date:			**Expiry date:**	
Has the manufacturer been informed?	☐ **No**		☐ **Yes, date:**	

B. 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:**		
Description:		
☐ **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**

C. Reporter Details

Name:	
Profession:	**Organization:**
Address:	**E-mail:**
Phone / Mobile:	**Fax:**
Signature:	**Date:**

What should be asked regarding drug quality?

1. Was the product stored correctly? (To exclude incorrect storage as the cause of the suspected defect)
2. If the defect is visible, was the defect identified in a new previously unopened container or had the container previously been used? (To exclude user errors such as product mix-ups)
3. Are there other unopened containers of the same batch available, which could be checked?
4. If the product requires preparation, such as addition of a diluents, was the correct procedure followed and/or correct diluents used?
5. If the product is used with a medical device, could the device be the cause of the incident?

- We realize that filling this form requires time to complete, but reporting product quality defects are indispensable for safe use of medicines. The SFDA can judge the quality and safety of medicinal products in Saudi Arabia only if sufficient information is provided.

- **Confidentiality:** Reporter's and patient's identity are held in strict confidence by SFDA and protected to the fullest extent of the law, information provided by the reporter will be strictly protected and will not be used in any way against him.

This form can be used by: • Physician. • Pharmacist. • Dentist. • Nurses. • Other healthcare providers. **Use this form to report product quality defect for:** • Suspected counterfeit product. • Suspected contamination. • Questionable stability. • Defected components. • Poor packaging or labeling. • Therapeutic failure.	**How to report:** • Fill out the reporting form. • Attach additional information, if needed. • Use a separate form for each product. **Please submit completed forms to:** ▪ **3292 Northern Ring Road – Alnafal District.** **Riyadh 13312-6288** ▪ **Fax: +966-11-205-7662** ▪ **website: www.sfda.gov.sa** ▪ **E-mail: npc.drug@sfda.gov.sa**

Thank You