Jal Pharma

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. Patient Details

Patient Name or initial (Optional):	**Date of birth:**	**Age:**	**Weight:**
Medical Record No:	**Health Institution :**		**Sex: □ M □ F**

B. Product Details

Product name (Generic & Brand):		
Package size:	**Strength:**	**Dosage form:**
Batch number:		
Manufacturer:		
Manufacturing date:	**Expiry date:**	

C. Type of Quality Problem

☐ **Therapeutic Failure**	☐ **Packaging**	☐ **Physical, chemical or microbial changes**	☐ **Other**

Description:

D. Reporter Details

Name:	
Profession:	**Organization:**
Address:	**E-mail:**
Phone:	**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 SBD can judge the quality and safety of medicinal products in Yemen Republic only if sufficient information is provided.

- **Confidentiality:** Reporter's and patient's identity are held in strict confidence by SBD 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.

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:

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Thank you