Supreme Board of Drugs &Medical Appliances Head Office Aden

National Pharmacovigilance Center

المركز الوطني للتيقظ و السلامة الدوائية
National Pharmacovigilance Center

الهيئة العليا للأدوية والمستلزمات الطبية
المركز الرئيس -عد ن
المركز الوطني للتيقظ والسلامة الدوائية

Date received:
By:

Pharmaceutical Products Quality Reporting Form
(Form NO. PQ-1)

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

A. Patient Details

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

B. Product Details

Type of product:	D Drug	ovaccine	o Herbal	o 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?	D No		D Yes, date:	

C. Type of Quality Problem

D Packaging	D Physical, Chemical or Microbial changes	D Questionable stability
D Suspected counterfeit product	D Suspected contamination	D Defective components
D Product confusion (caused by name, labeling, desian or packaaina}	D Labeling problems (caused by printing errors \ omissions}	
D Other:		
Description:		

D. 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 SBDMA can judge the quality and safety of medicinal products in Republic of Yemen 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.

Use this form to report adverse reactions from:

- **Medications (drugs or biologicals).**
- **Vaccines.**
- **Herbal remedies.**
- Cosmatics

Howto report:

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

This form can be used by:

- Physician.
- Pharmacist.
- Dentist.
- Nurses.
- other healthcare providers.

Please submit completed forms to:

National pharmacovigilance center

Head Office Aden:

-Tel. 8000860-02276860 Fax. 237780

-WhatsApp: 730109319

- Email : info@ysbda.com

Phone Application: Salamtok

الغذاء والدواء سلامتك SALAMTOK

Adress:

Supreme Board Head Office il Aden:

Aden I Khormakser I in front of AdenInternational Airport and Beside Aden public health and population office.

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-Email : Ynpvc@ysbda.com

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Taiz Branch Tel: 04-236208

Almukala Branch:

Tel: 05-321047 , 05-321029 , Fax: 05- 306018

Thank You