Republic of Yemen
Ministry of Public Health and Population
Supreme Board of Drugs
& Medical Appliances
Yemeni Center for Pharmacovigilance
and Medical Safety

الجمهورية اليمنية
وزارة الصحة العامة والسكان
الهيئة العليا للأدوية والمستلزمات الطبية
المركز اليمني للتيقظ والسلامة الدوائية

Adverse Drug Reactions(ADRs)Reporting Form
For Health Care Professionals (ADR-1)

A. Patient Details

Patient name or initial (Optional):	Date of birth:	Height:	Weight:	Health Institution:	Age: Sex: □ M □F
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B. Suspected Drug(s) / Vaccine(s)/ Herbal(s) /Cosmetic(s) and all other drugs used.

		Drug name"Generic &Brand"	Manufacturer and batch No.	Dose / Route / Frequency	Start date	End date	Purpose of use
Suspected	1						
	2						
	3						
Concomitant	1						
	2						
	3						

C. Adverse Drug Reaction

Adverse event including relevant tests/lab data and dates	Other relevant history, including preexisting medical conditions *(diagnosis, allergies, pregnancy, hepatic, renal etc)*
Date of event started:	Date of event disappeared, if applicable:

D. Action Taken

□Drug withdrawn. □ Dose reduced. □ Dose increased. □ Dose not changed. □ Unknown. □ Not applicable.

E. Outcome of ADR (Tick all applicable)

The patient	□ Recovered, date:	□ Recovering	□No improvement	□ Fatal □Unknown
Event subsided after stopping (dechallenge)			□No	□ Yes □ Unknown
Event reappear after reintroducing (rechallenge)			□No	□ Yes □ Not applicable
Specific antagonist or treatment used:			□No	□Yes, specify:----------

F. Seriousness of ADR (Tick all applicable)

□ Patient died, date: □ Life threatening □ Permanent disability
□ Hospitalization □ Prolonged hospitalization more than 24 hr. □ Congenital anomaly
□ Required intervention to prevent permanent impairment/ damage □ Required Emergency Room (ER) visit
□ Cancer □ Others……

G. Reporter Details

Reporter name :		Profession (Specialty):	
Address:		E-mail:	
Phone / Mobile:	Fax :	Date:	Signature:

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Dear healthcare professional:

- We realize that filling this form requires time to complete, but reporting adverse drug reactions are indispensable for safe use of medication. The SBDMA can judge the safety of medicinal products in Yemen only if sufficient information is provided.
- **Confidentiality:** Reporter's and patient's identity are held in strict confidence by SBDMA 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 / her.
- **Adverse Drug Reaction (ADR)** is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.
- **A serious adverse event or reaction** is any untoward medical occurrence that at any dose:
  - results in death
  - requires hospitalization or prolongation of existing hospitalization
  - results in persistent or significant disability/incapacity
  - is life-threatening

This form can be used by: • Physician. • Pharmacist. • Dentist. • Nurses. • Other healthcare providers. **Use this form to report adverse reactions from:** • Medications (drugs or biologicals). • Vaccines. • Herbal remedies.	**How to report:** • Fill out the reporting form. • Attach additional information, if needed. • Use a separate form for each ADR. **Please submit completed forms to:** ▪ **Fax: 619171** ▪ **E-mail: ypc@sbd-ye.org** ▪ **Phone 770210538-01221475-733651786**