

Date received:  
By:

**Adverse Drug Reaction (ADR) Reporting Form  
For Health Care Professionals  
Form NO. ADR-1**

**A. Patient 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

**B. Suspected Drug(s) / Vaccine(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 Description**

Adverse event including relevant tests/lab data and dates	Other relevant history, including preexisting medical conditions ( <i>diagnosis, allergies, pregnancy, hepatic, renal etc</i> )
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Drug withdrawn.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  Unknown  
 Event subsided after stopping (dechallenge)  No  Yes  Unknown  
 Event reappear after reintroducing (rechallenge)  No  Yes  Not applicable  
 Specific antagonist 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  
 Other.....

**G. Reporter Details**

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

**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 SFDA can judge the 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 / 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

<p><b>This form can be used by:</b></p> <ul style="list-style-type: none"><li>• Physician.</li><li>• Pharmacist.</li><li>• Dentist.</li><li>• Nurses.</li><li>• Other healthcare providers.</li></ul> <p><b>Use this form to report adverse reactions from:</b></p> <ul style="list-style-type: none"><li>• Medications (drugs or biologicals).</li><li>• Vaccines.</li><li>• Herbal remedies.</li></ul>	<p><b>How to report:</b></p> <ul style="list-style-type: none"><li>• Fill out the reporting form.</li><li>• Attach additional information, if needed.</li><li>• Use a separate form for each ADR.</li></ul> <p><b><u>Please submit completed forms to:</u></b></p> <ul style="list-style-type: none"><li>▪ <b>3292 Northern Ring Road – Alnafal District. Riyadh 13312-6288</b></li><li>▪ <b>Fax: +966-1-205-7662</b></li><li>▪ <b>website: <a href="http://www.sfda.gov.sa">www.sfda.gov.sa</a></b></li><li>▪ <b>E-mail: <a href="mailto:npc.drug@sfda.gov.sa">npc.drug@sfda.gov.sa</a></b></li></ul>
--	--

**Thank you**