Date received:
By:
Country:
Case Unique Serial #:
Case # in Log sheet:

Adverse Drug Reaction (ADR) Reporting Form

Patient Details

Patient name or Initial: **Health Institution:** **Medical Record No:**	**Date of birth:** **Age:** **Age Group: ☐ Elderly ☐ Adult ☐ Pediatric**	**Gender:** **☐ Male** **☐ Female**

Suspected Product Information

Trade Name/ Generic Name	Strength	Indication	Dose/ Frequency	Route	Duration	Start Date	End Date	Batch No.

Adverse Event Information

Adverse Event Description	Event Onset Date	Event End Date	Outcome	Causality
			☐Recovered ☐Recovering ☐Not Recovered ☐Unknown ☐Fatal ☐Recovered W/sequelae	☐ Related ☐ Not Related ☐ Not Reported
			☐Recovered ☐Recovering ☐Not Recovered ☐Unknown ☐Fatal ☐Recovered W/sequelae	☐ Related ☐ Not Related ☐ Not Reported
			☐Recovered ☐Recovering ☐Not Recovered ☐Unknown ☐Fatal ☐Recovered W/sequelae	☐ Related ☐ Not Related ☐ Not Reported

Diagnostic & Lab Values, Treatment Medication (associated with adverse event(s))

ACTION Taken: What happened after adverse reaction?

☐Drug discontinued ☐Dose reduced ☐Dose increased ☐Dosage maintained ☐Unknown

Medical History / Was there a relevant Medical History? ☐ Yes ☐ No

Medical History Term Including (Medical, Surgical, Smoking & Alcohol)	Onset Date	End Date

Seriousness

☐Serious ☐Non-Serious ☐Unknown

If serious indicate even seriousness criteria:

☐Death, Date: ☐Life threatening ☐Permanent disability ☐Hospitalization
☐Prolonged hospitalization ☐Congenital anomaly ☐Required intervention to prevent permanent impairment/damage

☐Other: _____

Concomitant Drugs

Were any concomitant drugs taken? ☐ Yes ☐ No

Concomitant Drug Name	Indication	Dose/Route/Frequency	Start Date	End Date

Pregnant? ☐ Yes ☐ No

Trimester or date after last menstrual period when exposure to the Product occurred:

Expected due date:

Any known pregnancy risk factors (e.g., history of miscarriage):

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

To be filled by Pharmacovigilance Department:

Date of receipt information: _____ **By:** _____ **Country:** _____	**Follow up information requested:** ☐ **Yes** ☐ **No**
Source type: ☐ **Spontaneous** ☐ **Literature study**	☐ **Initial report** ☐ **Follow-up report**