ANNEX 1: FORM FOR ADRs reported in written form

RECEIPT DATE	**TIME OF RECEIPT**
PATIENT INFORMATION Initials: Age:	Sex: Duration:
Suspect medicine **Product Name:** **Daily Dose:** **Route of administration:** **Duration of administration:**	Indication:
CLASSIFICATION OF REPORT:	
☐ Pregnancy ☐ Lactation ☐ Lack of efficacy ☐ Overdose ☐ Medication error ☐ Misuse ☐ Abuse	☐ Off label use ☐ Drug/food product interaction ☐ Falsified (counterfeit) product ☐ Unexpected therapeutic benefit ☐ Occupational exposure ` ☐ Quality Defect ☐ Other……..
CONCOMITTANT MEDICATION	**Product Name:** **Daily Dose:** **Route of administration:** **Duration of administration:**
MEDICAL HISTORY	
OUTCOME of reaction ☐ **Non-Serious** ☐ **Serious** **If serious please thick off seriousness criteria:** ☐ **Hospitalization** ☐ **prolongation of hospitalization**	☐Stopped ☐ Treatment continues ☐ Reduced dose ☐ Unknown ☐ recovered without sequelae ☐ ADRs was treated ☐ ADR is not treated

☐ **life-threatening condition** ☐ **congenital anomalies** ☐ **significant / permanent disability** ☐ **other medical significance / requiring intervention** ☐ **none of the above**	☐ healed with consequences ☐ treatment of ADRs continues ☐ unknown ☐ death-date
REPORTER	
Physician/Name: Assistant: Other (specify):	Tel: E-mail:
MEDICINAL PRODUCT:	MA NUMBER:
BATCH NUMBER:	
DESCRIPTION OF ADRs	

Name of contact person: _____

Signature

ANNEX 2: FORM FOR ADRs reported by phone, fax, OR ANSWERING machine

FORM FOR REPORTING ADRs RECEIVED BY PHONE	
PATIENT INFORMATION Initials: Age:	Sex: Duration:
Suspect medicine **Product Name:** **Daily Dose:** **Route of administration:** **Duration of administration:**	**Indication:**
CLASSIFICATION OF REPORT: ☐ Pregnancy ☐ Lactation ☐ Lack of efficacy ☐ Overdose ☐ Medication error ☐ Misuse ☐ Abuse	 ☐ Off label use ☐ Drug/food product interaction ☐ Falsified (counterfeit) product ☐ Unexpected therapeutic benefit ☐ Occupational exposure ` ☐ Quality Defect ☐ Other……..
CONCOMITTANT MEDICATION	**Product Name:** **Daily Dose:** **Route of administration:** **Duration of administration:**
MEDICAL HISTORY	
OUTCOME of reaction ☐ **Non-Serious** ☐ **Serious** **If serious please thick off seriousness criteria:** ☐ **Hospitalization**	☐Stopped ☐ Treatment continues ☐ Reduced dose ☐ Unknown ☐ recovered without sequelae ☐ ADRs was treated ☐ ADR is not treated

☐ **prolongation of hospitalization** ☐ **life-threatening condition** ☐ **congenital anomalies** ☐ **significant / permanent disability** ☐ **other medical significance / requiring intervention** ☐ **none of the above**	☐ healed with consequences ☐ treatment of ADRs continues ☐ unknown ☐ death-date

Product:	MA Number:
Batch:	

Contact person :

Patient _____Physician _____Assistant _____

Others_____Specify:_____

Date/Hour:

Report:

Necessary follow-up

Signature _____

Name: