CONFIDENTIAL

SUSPECTED SIDE EFFECTS REPORTING FORM

*FIELDS ARE MANDATORY. Please fill all fields as completely as possible.

Version 1.0

PATIENT INFORMATION

*Patient's Name or Initials:_____ *Sex: ☐Male ☐Female Weight (kg): _____ Height (cm): _____

*Age (at time of onset): _____ Date of Birth (dd/mm/yyyy): ____/____/_____

Medical record number: _____ Patient's address _____

SUSPECTED MEDICINES / VACCINES

*Medicine/Vaccine (Reg. No. or Brand, if any)	Batch/Lot No.	Dosage & frequency	Route	Date started dd/mm/yyyy	Date stopped dd/mm/yyyy	Reason for using
				___/___/_____	___/___/_____	
				___/___/_____	___/___/_____	
				___/___/_____	___/___/_____	

SIDE EFFECT(S) / ADVERSE REACTION(S)

*Date started (dd/mm/yyyy): ____/____/_____ time:_____

*Describe the side effects or reaction or problem:

Regarding the severity grading: was the event considered to be Mild, Moderate or Severe?

Relevant medical history and concurrent condition:
(Pertinent information to understand the case such as disease, conditions such as pregnancy, allergies, surgical procedures, psychological trauma, etc.)

Results of tests and procedures:
(Tests and procedures performed to diagnose or confirm the reaction/event, including those test done to investigate or to exclude a non-drug cause/ Results of test/procedures may be attached)

Do you consider the reaction to be serious? ☐yes ☐no

If yes, reason

☐death (date:_____) ☐life-threatening

☐hospitalization/prolonged (date of admission:_____) ☐disabling

☐congenital-anomaly ☐other medically important condition

Was this a medication error? ☐yes ☐no

Action taken:
☐medicine withdrawn
☐dose reduced
☐no change

Is treatment given? ☐yes ☐no
If yes, please specify:
_____

Outcome of reaction
☐recovered (date:_____)
with sequelae?
☐no
☐yes, describe:_____
☐not yet recovered
☐fatal
☐unknown

Did the reaction recur on readministration of suspected medicine(s)?
☐yes ☐no ☐not applicable

List all other medicines/vaccines taken at the same time (including diluent)

Medicine/Vaccine(DR-XY No. or Brand, if any)	Batch/Lot No.	Dosage & frequency	Route	Date started dd/mm/yyyy	Date stopped dd/mm/yyyy	Reason for using

☐

REPORTER INFORMATION

***Name:** _____

Address:_____

***Contact/Mobile No.:** _____

Email:_____

Signature/ initials: _____

***Date of report (dd/mm/yyyy):** ___/___/_____

***Reporter qualification:**

☐**physician** ☐**nurse**
☐**pharmacist** ☐**dentist**
☐**other health professional**
☐**patient/consumer**