	SUSPECTED ADVERSE REACTION TO MEDICINES/BORDERLINE PRODUCTS - CASE REPORTING FORM	Report number (NMRA use only)
	Suspect and adverse event, please complete this white card. Do not put off reporting because some details are not known. Submission of a report does not constitute an admission that medical personnel or the product caused or Contributed to the adverse reaction. Identity of the patient and /or the reporter is kept strictly confidential. **Send the filled form to:** **National Medicines Regulatory Authority, State Engineering Corporation, 2nd Floor, No 130, W. A. D. Ramanayake Mawatha, Colombo 02** **Email: pharmacovigilance@nmra.gov.lk Fax: +940112689704. Tel: +940112698896/7**	State sector ☐ Private sector ☐

A. PATIENT INFORMATION

BHT/ Record no:	Name & address (optional):	Date of birth: Age :	Gender		Weight	Ethnicity :
			Female			
			Male			

B. SUSPECTED MEDICINE

Generic name :	Dose	Route of administration	Therapy date	Therapy begun :
Brand name:				
Batch number:	Frequency			Therapy stopped :
Expiry date:				

Manufacturer name and address :

Diagnosis for use:

C. ADVERSE DRUG REACTION (if you suspect the adverse event is due to poor quality of the product please provide samples to the NMQAL) (in case of anaphylaxis please use anaphylaxis case reporting form)

Date of onset of event:		Time taken to onset of event following the suspected medicine:	

Describe event:

Lab investigation if any:

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Seriousness of the event : Mild ☐ Moderate ☐ Severe ☐ Fatal ☐

Outcome of the reaction : (Please select the suitable box)

Recovered		Life threatening		Medically significant (specify)		hospitalization	
Hospitalization prolonged		Congenital anomaly		Birth defect		disability	
Permanent damage		Required intervention to prevent permanent damage				Death (date of the death)	

Result of discontinuation of suspected drug (Please select the suitable box)

Improved		Disappeared		Persisted		Not known	

Result of reintroduction of drug : Reappeared the reaction	Yes		No		Not known		

Alternative diagnosis:

Risk factors present : (Please select the suitable box)

Cardiac dysfunction	Renal dysfunction	Hepatic dysfunction	Previous allergies	Smoking	Alcohol	Drug addicted	Pregnant	Other (specify)

D. OTHER MEDICINES TAKEN AT TIME OF REACTION WITH THERAPY DATES (EXCLUDE TREATMENT OF EVENT): (Please mentioned the time of each medicine taken)

Medicine name	The date and time given to the patient

E. REPORTER DETAILS : (DOCTER/PHARMACIST/NURSE/OTHER)

Name of the reporter :

Hospital name and address:			Ward	
Contact details	Telephone number		Email	

Signature

Date of reporting

Stamp (if available)