Pharmacovigilance Department

Form: Collection of ADR information.

MACLEODS

ADVERSE EVENT REPORT

PATIENT INFORMATION:

Patient initials: COUNTRY:	**Date:**

REPORT TYPE: ☐ Initial ☐ Follow-up							
DATE OF BIRTH	AGE	RACE	SEX	HEIGHT	WEIGHT	ONSET DATE	RECOVERY DATE
DD/MM/YYYY			☐ Male			DD/MM/YYYY	DD/MM/YYYY
			☐ Female				

ADVERSE EVENT INFORMATION :

ADVERSE EVENT(S) IN MEDICAL TERMS (diagnosis, if possible)

Description of event:

Seriousness criteria
Check all appropriate to event

- ☐ Patient died
- ☐ Involved or prolonged inpatient hospitalization
- ☐ Involved persistent or significant disability or incapacity
- ☐ Life-threatening
- ☐ Congenital anomaly/birth defect
- ☐ Other significant medical events

HISTORY :

PATIENT'S RELEVANT MEDICAL HISTORY (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

TEST / LABORATORY FINDINGS (enter only those findings necessary for AE diagnosis or course description)

SUSPECT DRUG INFORMATION :

Product Name		Manufacturer	Batch/lot number	Expiry date	Dose	Route of use	Frequency	Therapy dates (from) (To)		Indication
Brand name	Generic Name							DD/MM/YYYY	DD/MM/YYYY	

CONCOMITANT DRUGS

DRUG NAME(S)		DOSE	THERAPY DATES (from) (To)		REASON FOR USE
Brand name	Generic Name		DD/MM/YYYY	DD/MM/YYYY	

ACTION TAKEN WITH SUSPECT DRUG (mark all as appropriate)

☐ No Action Taken ☐ Withdrawn ☐ Treatment taken

Did Reaction Disappear After Stopping of Drug?
☐ Yes ☐ No ☐ Not Applicable ☐ Unknown

Did Reaction Reappeared After Restarting of Drug?
☐ Yes ☐ No ☐ Not Applicable ☐ Unknown

OUTCOME OF THE PATIENT/AE

☐ Completely Recovered | Date of recovery: DD/MM/YYYY | ☐ Condition still present and unchanged

☐ Recovered with sequelae | ☐ Condition deteriorated

☐ Condition improving | ☐ Death Autopsy: ☐ No ☐ Yes

ASSESSMENT OF CAUSALITY

☐ Probable ☐ Possible ☐ Not Related ☐ Unknown

REPORTER'S INFORMATION :

NAME, ADDRESS, TELEPHONE NUMBER AND EMAIL OF REPORTER

DATE OF THIS REPORT
DD/MM/YYYY

☐ HCP ☐ CONSUMER ☐ OTHER

Signature:

Senders Contact details:

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