ADVERSE EVENT (AE) REPORT FORM

UID number (for office use only): _____ Date of report: _____

Type of report: ☐ Initial ☐ follow up/number (Please specify) _____

Reporter Details: Reporter is HCP: ☐ physician ☐ patient ☐ nurse ☐ others (Please specify) _____

Consumer: ☐ patient ☐ relative ☐ friend ☐ others (Please specify) _____

Name: _____ Qualification/designation:_____ Address: _____
City_____ State_____ Zip code:_____ country_____ Contact number: _____ Email: _____

Permission to contact treating physician (If reporter is a consumer): ☐ Yes ☐ No ☐ Unknown (If YES, provide contact details of physician below)

Treating Physician Details:

Name: _____ Contact number:_____

Email:_____ Address:_____
city:_____ state:_____ Zip code:_____ Country:_____

Patient detail: Name/Initial: _____Age at the time of onset of AE: ____ years DOB:_____ Sex: ☐ M ☐ F ☐ Unknown Weight: ____ kg/lbs
Hospital registration number (If any):_____

Adverse Event details						
Adverse Event(s)	Date of onset DD/MM/YY	*Causal relationship with the suspect drug	*** Outcome	Date of resolution /ongoing	Severity (Mild/Moderate/Severe)	**Seriousness (serious/nonserious)

*Select the appropriate causality term (refer page 4 for assessment criteria of below mentioned causality): **CR**; certainly related, **POR**; possibly related, **PRR**; probably related, **ULR**; Unlikely related, **UC**; unclassified, **UA**; unassessable **NR**; Not related

****If serious** select seriousness criteria: ☐ Death ☐ Disability ☐ Life threatening ☐ Medically significant ☐ Congenital Anomaly/Birth Defect ☐ Hospitalization ☐ Prolongation of hospitalization

*** Select the appropriate outcome of the event term: **R**- Resolved, **I**- Improving, **P**- Persisting, **U**- Unknown, **RS**- Resolved with Sequelae

If Hospitalized provide
Date of admission_____ Date of discharge_____
Attach the copy of discharge summary with this form.

Suspect drug details

Prescribed by Physician ☐ Yes ☐ No

Product name with dosage form and strength. Trade name (generic)	Indication	Route/ formulation/frequency/strength	Batch No.	Mfg. Date	Expiry date	Therapy date	
						Start date DD/MM/YY	Stop date DD/MM/YY

Is there any product quality complaint: ☐ Yes ☐ No (If YES please provide brief description in narrative section)

Action Taken with suspect drug (If more than one AE kindly mention in Narrative section): ☐ drug withdrawn ☐ reducing drug dose ☐ interrupting drug dose ☐ no change in drug dose ☐ drug dose increased ☐ NA
Reaction subsided after action taken: ☐ Yes ☐ No ☐ NA
Reaction reappeared after re-introducing drug ☐ Yes ☐ No ☐ NA

Death Information

Date of Death (DD/MM/YYYY): _____	Autopsy: ☐ Yes ☐ No ☐ Unknown
Cause of Death: _____	Autopsy result (if yes):_____

Concomitant Medications

Product name Trade name (Generic name)	Indication	Route/ formulation/ frequency/strength	Therapy dates (DD/MM/YY)		Continued (Yes/No)
			Start date	Stop date	

Relevant Medical History Medical history (in addition to indications mentioned above): ☐ Yes ☐ No

Medical History	Start date	Stop date (Ongoing/Past history)

Any laboratory test performed: ☐ Yes ☐ No

Test name	Result	Normal range	Date performed

Brief Narrative (Description of adverse event, treatment for adverse event if any and additional information missing in the form):

Response provided to the reporter:

Note: In-Case of diagnostic test/lab test/abnormal ECG/biopsy etc. attach the copy of reports with this form.

_____
(PVD personnel signature with date)

Email us at:
drugsafety@biocon.com

***The assessment criteria of the various categories (WHO-UMC causality Categories)**

CAUSALITY TERM	ASSESSMENT CRITERIA*
Certain/Definitely related	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/ Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified