Pharmacovigilance Department

ADVERSE EVENT REPORTING FORM

Type of Report: ☐ Initial case ☐ Follow up

(A) Patient Details*

Patient Initials	_____[ex. Vishal Kumar Sharma VKS]	Country	
Age/ Date of Birth		Weight	
Gender	☐ Male ☐ Female ☐ Other	Pregnant	☐ Yes ☐ No ☐ Unknown

(B) Suspected Medication(s) *

S. No.	Product Name		Manufacturer name	Marketer Name	Batch number/ Expiry Date	Dose, Route & Frequency (OD/BD etc.)	Therapy Start date DD/MM/YYYY	Therapy Stop date DD/MM/YYYY	Indication	# Action Taken
	Brand Name	Generic Name with strength/ formulation								
1.										
2.										
3.										

Select appropriate action taken:
Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Did event abated after drug withdrawn/ dose reduced? ☐ Yes / ☐ No / ☐ Unknown / ☐ Not applicable	Did event reappeared after reintroduction? ☐ Yes / ☐ No / ☐ Unknown / ☐ Not applicable

Concomitant medications (Any other medications consumed along with our company drugs):

Drug Name	Dose & Frequency	Route	Therapy dates		Reason for use
			From	To	

(C) Adverse Event Details *

Adverse event	Date of event Onset	Date of event stopped	##Outcome

Select outcome of the event: *Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal*

Is the adverse event serious? ☐ Yes / ☐ No

If yes, please indicate why it is serious? (Check all that apply)

☐ Death ☐ Life threatening ☐ Hospitalization-Initial /Prolonged

☐ Congenital anomaly/birth defect ☐ Disability ☐ Other important medical event

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If hospitalized provide: Date of admission _____ Date of discharge _____ Attach the copy of discharge summary with this form.	If Death provide: Date of death DD/MM/YYYY _____ Cause of death _____ Autopsy: ☐ Yes ☐ No ☐ Unknown Autopsy result (If yes): _____
Description of adverse events: (including sign and symptoms with specific diagnosis, treatment):	
Relevant Lab test Details (with dates, results and normal range) :	
Other relevant history including pre-existing medical conditions: (e.g. allergies, smoking, alcohol use, liver/kidney problems etc.)	

(D) Reporter details*	
Name:	Occupation:
Email:	Phone No.
Address:	Date of this report:
Consent to contact Healthcare Professional (HCP) / Prescribing Physician: ☐ Yes ☐ No	
If yes, provide contact Healthcare Professional (HCP) / Prescribing Physician details	
Name:	Qualification:
Address:	
Email:	Phone No.

* *Mandatory Fields for Adverse Event Reporting Form.*

Please send the complete form to:

Registered office: **Maya Biotech Pvt Ltd.** Plot No. 46, Industrial Area Phase-II, Chandigarh-160002, INDIA or *email* the scanned copy to: Email id pharmacovigilance@mayabiotechindia.com, regulatory01@mayabiotechindia.com

If any additional data, then please attach with this form:

This section filled by M/s Maya Biotech Pvt Ltd Pvt. only:	
Report ID: _____	Receipt Date*:* _____
Name and Signature of receiving PV-personnel:	