ADVERSE EVENT REPORTING FORM (FOR MARKETER)

Type of Report	**This section filled by Synokem only**
☐ Initial case ☐ Follow up case / Number (Please Specify) _____	Report ID: _____ Receipt date: _____

(A) Patient Details*

Patient Initials _____ Ex. Ramesh Kumar Mishra (RKM)				Country	
Age at time of event			or	Date of Birth DD/MM/YYYY	
Weight (in kg/lbs)		Height (cm/ft)		Pregnant	☐ Yes ☐ No ☐ Unknown
Gender	☐ Male ☐ Female ☐ Other			Date of LMP (Last Menstrual Period)	

(B) Suspected Medication(s) *

S. No.	Product Name		Manufacturer 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	## Causality Assessment
	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Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Select appropriate Causality Assessment: As per WHO-UMC causality categories

Did event abated after drug withdrawn/ dose reduced?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

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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

If hospitalized provide:	If Death provide:
Date of admission _____	Date of death DD/MM/YYYY _____
Date of discharge _____	Cause of death _____
Attach the copy of discharge summary with this form.	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 (Marketer)*

Name:	
Address:	
Email:	Phone No.
Date of this report :	Signature:

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.

Please Send the complete form to:

Registered office: M/s Synokem Pharmaceuticals Ltd., Pharmacovigilance department, 14/486, Sunder Vihar, Outer Ring Road, Paschim Vihar, New Delhi-110087, India.
Or email the scanned copy to **pv@synokempharma.com / ska@synokempharma.com**

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

Signature and name of receiving PV-personnel at Synokem	

** Mandatory Fields for Adverse Event Reporting Form.*