SAMI DRUG SAFETY REPORTING FORM

imed — Your partner for safer use of medicines

To be filled by SAMI Drug Safety		To be filled by Reporter	
SAMI AE number	MCN number (if applicable)	Patient Registration ID (if applicable)	First Contact Date:
Report type: ☐ Initial ☐ Follow-up: No:	SAMI MI number (if applicable)	Does patient give consent to obtain follow-up information from HCP? ☐ Yes ☐ No ☐ Unknown	Latest contact Date:

REPORTER TYPE

☐ Doctor (specialty: _____)
☐ Pharmacist
☐ Nurse
☐ Social Media (e.g. Facebook, Twitter, Website)
☐ Regulatory Authority
☐ Company Representative
☐ Consumer
☐ Literature
☐ Other (specify: _____)

PATIENT INFORMATION

Initials

Gender ☐ Male ☐ Female ☐ Unknown

Weight: ☐ lb ☐ kg

Height: ☐ inch ☐ cm

Date of Birth or Age (years) or Age Group
☐ Child (<18 yrs)
☐ Adult (≥18 yrs <65 yrs)
☐ Elderly (≥ 65 yrs)

Country: ☐ Pakistan ☐ Other: Please specify

SUSPECT DRUG (s) DETAILS – use additional sheets if required

Drug Name	Indication	Dose	Route	Frequency	Start Date	Stop Date/ongoing	Batch / Iot No.	Manufacturer Name

Action taken due to the Adverse Event?
☐ None ☐ Dosage changed (specify _____) ☐ Discontinued ☐ Unknown

Corrective treatment?
☐ No ☐ Yes (specify: _____)

Did reaction abate after stopping drug/dose reduction?
☐ Yes ☐ No ☐ Unknown ☐ Not applicable

Was drug restarted after reaction abated?
☐ Yes ☐ No ☐ Unknown ☐ Not applicable

If yes, did reaction recur?
☐ Yes ☐ No ☐ Unknown ☐ Not applicable

ADVERSE EVENT (S) DETAILS - use additional sheets if required

Adverse Event (adverse event description, provide diagnosis if known)	Onset Date	Resolved / Improved Date	Seriousness (as per key below one or more)	Outcome
				1.☐ 2.☐ 3.☐ 4.☐ 5.☐ 6.☐
				1.☐ 2.☐ 3.☐ 4.☐ 5.☐ 6.☐

Outcome: 1. Death 2. Not Resolved 3. Resolved 4. Resolved with sequelae 5. Resolving 6. Unknown

Special Situation Report (SSR) Details – Did any of the following occur?

☐ Lack of Efficacy ☐ Off Label Use ☐ Misuse ☐ Abuse ☐ Overdose ☐ Medication Error
☐ Pregnancy Report ☐ Infant with AEs following exposure from Breastfeeding
☐ Occupational exposure with AE ☐ Drug Interactions ☐ Unexpected Benefits
☐ Transmission of Infectious Agents via the Product ☐ Medical Device Incident
☐ Counterfeit or Falsified Medicines

In case of potential event related to Lack of Efficacy, marked expected reason:
☐ Antimicrobial Resistance ☐ Drug Interaction ☐ Poor Treat Compliance
☐ Counterfeit ☐ Expired ☐ Under Dosing ☐ Improper Storage
☐ Other: specify: _____

In case of Medication Error (actual/potential):
☐ ME with AE ☐ ME without AE
Marked expected reason: ☐ Storage ☐ Prescription ☐ Dispensing
☐ Preparation for Admin ☐ Missed Dose ☐ Administration by HCP/Patient/Consumer
☐ Other: specify: _____

Key for seriousness criteria classification

1. Death: Date of Death:
Was autopsy performed? ☐ Yes ☐ No (If yes attach report)
2. Life Threatening (immediate risk of death due to event)
3. Initial / Prolonged Hospitalization, provide dates: _____ to _____
4. Birth defects
5. Persistent or significant disability
6. Medically significant (Important Medical events that may jeopardize the patient and may require medical / surgical intervention to prevent the other outcome)
7. Non Serious
8. No seriousness criteria provided

CAUSAL RELATIONSHIP OF ADVERSE EVENT:

☐ Certain ☐ Probable / Likely ☐ Possible ☐ Unlikely ☐ Conditional /Unclassified ☐ Unassessable/Unclassifiable ☐ Not reported

CONCOMITANT DRUG(S) AND THERAPIES DETAILS - use additional sheets if required

Were any concomitant drugs/therapies used? ☐ Yes (specify below) ☐ No ☐ Unknown

Drug Name Indicate Form / Strength	Indication	Frequency	Route	Treatment Dates: Start	Treatment Dates: End (or ongoing)
					or ☐ ongoing
					or ☐ ongoing
					or ☐ ongoing

SUMMARY OF EVENTS / RELEVANT MEDICAL HISTORY DETAILS - use additional sheets if required (Please provide a short summary of the event(s) and include any treatment given, relevant medical history, risk factors, outcome, surgeries, allergies, any intervention given and pregnancy with date of last period)

LABORATORY DATA/ INVESTIGATIONS DETAILS - use additional sheets if required

Lab test	Result	Unit	Date of test	Normal range

REPORTER DETAILS:

Name: _____ **Address:** _____
Email address: _____ **Telephone number:** _____ **Fax number:** _____
Signature: _____ **Date:** _____

Please email / fax / mail completed form within 24 hours of being aware of event

Email: safety@samikhi.com
Tel No (office and out of office hours): +92 21 34383400
Fax: +92 21 34382012 SMS/WhatsApp: 0336 4393299 (24/7 Operations)

Mail: SAMI Pharmaceuticals (Pvt.) Limited
Head Office: 34-C, Block 6, P. E. C. H. S., Karachi-75350, Pakistan

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