MEDINET
Pharmaceuticals Pakistan (Pvt) Ltd.

MEDINET SAFETY INFORMATION

SUSPECTED ADVERSE DRUG EVENT REPORTING FORM

This form is for voluntary/ spontaneous reporting of ADRs (Adverse Drug Reactions) of products marketed by Medinet Pharmaceuticals Pakistan (Pvt) Ltd.

FOR OFFICE USE ONLY

Company Recipient Name: _____

PV Recipient Name: _____

Date Received: _____

PV Reference No: _____

A. PATIENT INFORMATION

1. Patient Name: _____ 2. Patient identification Number (If any): _____

3. Sex: ☐ Male ☐Female 4. If female, Pregnant: Yes / No (Trimester ☐) 5. Age (years): _____ 6. Weight (Kg): _____

7. Allergies (if any): _____ 8. Liver/Kidney Dysfunction (If Yes, extent):_____

B. PRODUCT INFORMATION

Brand Name	Generic Name	Strength	Batch No	Expiry Date	Dose & Frequency	Route of Administration	Start Date	Stop Date	Prescribed for

1. Reaction abated after use stopped or dose reduced?: Yes/ No (If dose changed, please specify dose:) _____

2. Reaction reappeared after reintroduction? Yes/ No 3. Product available for evaluation: Yes/ No

C. EVENT/ REACTION(S) INFORMATION

1. Date of Onset (DD/MM/YY):_____

2. Describe the Adverse drug event/reaction, Problem or error with relevant tests/Laboratory data with dates

3. Do you consider the problem related to which of the following:

☐ Adverse Drug Event/Reaction
☐ Quality Problem
☐ Medication Error
☐ Others (please specify) _____

4. Outcome:

☐ Fatal ☐ Recovering ☐Unknown:
☐ Recovered ☐Other: _____

5. Do you consider this event serious: Yes / No

If yes please indicate why? ☐ Patient died due to reaction ☐ Life threatening ☐ Caused disability/incapacity ☐ Involved / prolonged inpatient hospitalization ☐Congenital anomaly/Birth Defects

Other Serious (Medically Important Condition): please give details: _____

D. OTHER CONCOMITANT DRUG(S)/VACCINE(S)/ALTERNATIVE MEDICINE(S) & PATIENT HISTORY

1. Concomitant Drugs used (if any) (exclude those used to treat reaction) +

Brand Name	Generic Name	Strength	Batch No	Expiry Date	Dose & Frequency	Route of Administration	Start Date	Stop Date	Prescribed for

2. Other relevant history of the patient (Allergies, Smoking, Alcohol Use, Hepatic/Renal Problems, and Pre-Existing Medical Problems etc.:

E. MEDICAL DEVICE(S) INFORMATION

Fill this area for suspected Device only (use additional pages if necessary):

Medical Device Brand Name/ Common Name	Batch No	Model No	Expiry Date	Unique Identifier No	Operator of the Device	If Implanted enter date	If Explanted enter date
					☐Health Professional ☐Technician ☐ Patient ☐ Other_____		

F. REPORTER INFORMATION*

1. Reporter's Name: _____ 2. Professional Address: _____

3. Contact Details: _____ 4. Email address: _____

4. Profession: ☐Physician ☐ Pharmacist ☐Nurse ☐ Patient ☐ Other_____

5. Date Reported: _____ 6. Signature: _____

*Compulsary Information + Additional pages can be used if required
Send signed filled form at Medinet.infoservices@gmail.com