AVP/PV/ADR/RF/QF/01

AMSON

Amson Vaccines & Pharma (PVT) LTD

Suspected Adverse Event Reporting Form

For Office use
Company Receipt No: .....
PV Receipt Name: .....
Date Received: .....
PV Reference No: .....

This form is for voluntary/ spontaneous reporting of adverse drug reactions of the products marketed by Amson Vaccines & Pharma (PVT) LTD.

A. Patient Information

Patient Initial Or Name: .....
Medical/ Hospital Reference (Identification) No: .....
Allergies (If any): .....
Age: .....
Sex: .....
Weight: .....
If Female, Pregnant: Yes / No
Kidney/ Liver Dysfunction (If yes, Please explain): .....

B. Product Information

Product Name & Generic Name with strength: .....
Route Of Administration: .....
Dose: .....
Batch No: .....
Indication/ Used For: .....
Start Date: .....
Dosage Form: .....
End Date: .....

C. Event Information

1. When the reaction started (DD/MM/YY: .....)
2. When recovery started (DD/MM/YY: .....)

3. Describe the reaction(s): (use additional pages if necessary):

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

5. Relevant test/ Laboratory data with dates: (use additional pages if necessary):

6. Do you consider the reaction(s) to be serious? Yes/ NO
If yes, please tick all that apply of following:
- Patient dies due to reaction:
- Life threatening
- Other serious Medical Important Conditions: (Please give details): .....
- Caused Disability/ Incapability
- Congenital anomaly/ Birth defects
- Involved/ Prolonged Inpatient Hospitalization

7. Reaction abated after use stopped or dose reduced?
Yes / No / Doesn't apply

8. Reaction reappeared after reintroduction?
Yes / No / Doesn't apply

9. Outcome:
- Fatal
- Recovering
- Continuing
- Others (Please Specify): .....
- Unknown
- Recovered

10. You consider the problem related to which of the following:
- Quality Problem
- If other (please specify): .....
- Medication Error
- Adverse Event/ Reaction

D. Other Drug(s) and History

1. Concomitant Drugs used (If any) (Exclude those used to treat reaction)

2. Other Relevant History (Diagnostics, Lab Tests, etc.)

E. Reporter Information

1. Reporter's Name: .....
2. Mailing Address: .....
3. Contact Details: .....
4. Date Reported: .....
5. Profession:
- Physician
- Nurse
- Other (Please Specify): .....
- Pharmacist
- Patient

6. Signature: .....

Send Signed Filled form to Pharmacovigilance Department, **Amson Vaccine & Pharma (PVT) Ltd.** Plant: 154, Industrial Triangle Kahuta Road, Islamabad, Pakistan

"This form neither has any legal value nor can be presented before any Court of Law as Evidence".

*Additional Pages can be used if required