Adverse Event Reporting Form

PATIENT INFORMATION

*Pt initials: _____	*Age: _____ years	*Gender: M ☐ F ☐	Weight: _____ kg ☐ / lb ☐
Ethnicity: _____	DOB: DD/MMM/YYYY	Pregnant: Yes ☐ No ☐ NA ☐	Height: _____ cm ☐ / in ☐

ADVERSE EVENT

***Adverse Event:**	**When was the event identified?** DD/MMM/YYYY
	Start date: DD/MMM/YYYY **End date:** DD/MMM/YYYY

SUSPECTED MEDICINE(S)

No.	*Name (brand/generic)	Batch no.	Expiry date	Route	Dose	Frequency	Start date	Stop date	Indication/Purpose
1							DD/MMM/YYYY	DD/MMM/YYYY	
2							DD/MMM/YYYY	DD/MMM/YYYY	

Description of the event:

(If this space is inadequate, use the next page)

Relevant tests / laboratory data with dates:

Relevant medical history and concurrent conditions:
Previous exposure to same drug: Yes ☐ No ☐

Seriousness: Serious ☐ Non-serious ☐ **Please specify reason for considering serious from the list below:**

1. Death ☐
2. Life threatening ☐
3. Disability *(significant/permanent)* ☐
4. Anomaly at birth ☐
5. Required hospitalization ☐
6. Prolonged hospitalization ☐
7. Other important medical event ☐

(specify)_____

_____

In case of death: Date of death: DD/MMM/YYYY

Cause of death: _____

_____

Post Mortem/ Autopsy Performed: ☐ Yes ☐ No

(If 'Yes', Please Attach Findings)

Action taken for the resolution of event:

1. Suspected medicine withdrawn ☐
2. Reduced dose of the medicine ☐
3. Symptomatic treatment ☐
4. Unknown treatment ☐
5. Specific treatment ☐
   Specify _____
   _____
6. None ☐

Outcome: (What happened to the event later?)

1. Recovered completely ☐
2. Recovering ☐
3. Recovered with sequela ☐
4. Not yet recovered ☐
5. Fatal ☐
6. Unknown ☐
7. Other ☐ _____

Did adverse event improve after stopping or reducing drug? Yes ☐ No ☐ Unknown ☐ Not Applicable ☐

Did adverse event reappear after reintroducing the drug? Yes ☐ No ☐ Unknown ☐ Not Applicable ☐

Do you think that the adverse event was caused by the suspected drug? Yes ☐ No ☐ Unknown ☐

Reason: _____

Concomitant medicine(s) (Which other medicine was the patient taking?)

No.	Name (brand/generic)	Dose regimen	Start date	Stop date	Indication/Purpose
1			DD/MMM/YYYY	DD/MMM/YYYY	
2			DD/MMM/YYYY	DD/MMM/YYYY	
3			DD/MMM/YYYY	DD/MMM/YYYY	
4			DD/MMM/YYYY	DD/MMM/YYYY	

REPORTER INFORMATION

***Name:**	***Phone no.**	***Address:**
		***Country:**
Occupation/ Designation:	**Sign & date:**	**Email id:**

***Mandatory fields**

(If more information is available, use next page)

To be filled by Pharmacovigilance unit of Bharat Serums and Vaccines Ltd.

Report Type: ☐ Initial ☐ Follow up, Number: ____	**Date of receipt:** _____	**Report ID:** _____

Bharat Serums and Vaccines Limited

Please send the completed form by e-mail to pv@bharatserums.com Or Fax it to +91- 22-45043355
You may send the completed form to: Clinical Research & Pharmacovigilance, Bharat Serums and Vaccines Ltd., 3rd Floor, Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai, 400708, INDIA.

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ADDITIONAL INFORMATION
Description of the event:
Details of relevant medical history (also include drug reactions, allergies, and/ or drug & alcohol abuse):
Additional investigations done after identification *(attach reports if necessary)*
Details of treatment: (Describe medical interventions and/or surgical treatments with dates)
Any other relevant information:

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