ADVERSE EVENT FOLLOWING IMMUNIZATION FORM

Patient's Details:

Patient Name:				Patient's Address:
Date of Birth:	DD/MM/YYYY	Age:	____(years)	
Height:	_____(cm)	Weight:	_____(Kg)	
Sex: M ☐ F ☐ If Pregnant, Specify the details:				Contact Number:

Reporter's Details:

Report's Name:		Reporter's Address:
Designation:		
Date of Patient notified to health system	DD/MM/YYYY	
Time of Patient notified to health system	HH:MM	Contact Number:

Vaccine Details:

Vaccine Name		Date of Vaccination:	DD/MM/YYYY	Time of Vaccination:	HH:MM
Route of Administration		Batch No		Dose	1st/ 2nd/ 3rd/4th/5th

Adverse event Details:

Local Reactions	Date	Time
☐ Pain		
☐ Swelling		
☐ Tenderness		
☐ Redness		
☐ Itching		
☐ Others(Specify):		

Systemic Reactions	Date	Time
☐ Fever		
☐ Chills/Rigors		
☐ Diarrhea		
☐ Vomiting		
☐ Seizures		
☐ Headache		
☐ Others(Specify):		

Duration Since Vaccination:
Event Details(attach additional sheets if required)
Treatment Details: (any tests or diagnostics performed, attach reports)
Opinion of the Doctor: (in relation to vaccine administration) Related ☐ Unrelated ☐
Outcome: Recovered ☐ Recovery ☐ Ongoing ☐ Not recovered ☐ Unknown ☐ Recovered with sequelae (Specify):
(any relevant documents please attach)

Signature of Doctor/Physician with Date and Stamp:

ADVERSE EVENT FOLLOWING IMMUNIZATION FORM (AEFI)- SERIOUS

Note: In case of event is serious, kindly share this form within 24 hours.

*☐ Initial report ☐ Follow-up report No: _____

*Date: _____

Product Name:	Country: INDIA	* Patient's Address available on file with the Doctor ☐Yes ☐No
* Patient's Name: _____		
*Reporting Doctor's Name & Reg. No:		Manufacturer's name: G. C. Chemie Pharmie Ltd.

*1 Patient's Vaccination Register No:_____	*2. Patient's Initials	*3. Gender ☐ M ☐ F	4. *Date of birth (DD/MM/YYYY) ____/_____/_____	*5. Height _____ cm	*6. Weight _____ Kg

7. Serious criteria if any

☐ Immediately Life threatening

☐ Required Hospitalization

☐ Medically significant

☐ Resulting in Persistent Significant Disability or congenital abnormality in fetus

*8. Vaccine Adverse Event Term (Signs/Symptoms/Diagnosis)	*9. Start date and Start Time	*10. Stop date and Stop Time	*11. Grade: The following codes should be used: 1 = Mild 2 = Moderate 3 = Severe 4 = Life-threatening 5 = Fatal	*12. Causal Relationship 1 = Not related 2 = Unlikely to be related 3 = Possibly related 4 = Probably related 5 = Definitely related
	___/____/_____ DD MM YYYY _____: _____ HH MM	___/____/_____ DD MM YYYY _____: _____ HH MM		

*13. Outcome

☐Complete Recovery ☐ Ongoing

☐ Recovered with sequelae, specify: ☐ Death,

☐ Unknown Autopsy Performed ☐ No ☐ Yes (if "Yes", Please attach report)

14. Describe event, treatment details etc. (Use additional pages if required) (Can provide a detailed Summary)

_____

_____

_____

_____

15. Additional Tests: ☐ Yes, Specify:_____ ☐ Reports attached

☐ No

*16. Vaccine Lot No #: _____	17. Route of Administration, Site of Administration, and Schedule/ Regime being followed.	18. Scheduled Dose:	*19. Date of First dose: (DD/MM/YYYY) ___/___/____ Date of Second dose: ____/___/____ Date of Third dose: ___/___/____	*20. Action Taken ☐ No Action Taken ☐ Medical Intervention ☐ Surgical Intervention ☐ Combined Medical & Surgical Intervention. ☐ Other.	*21. Action taken w.r.t Vaccine. ☐ No Action Taken ☐ Dose Reduced ☐ Dose Interrupted ☐ Dose Interrupted and Reduced ☐ Discontinued

22. Action regarding Vaccination Protocol:

☐ Patient still on vaccination schedule ☐ Patient withdrawn ☐ Not Applicable

23a. Concomitant Medications used to treat VAE: *(Doctor's Prescription page can be copied in lieu of completing this section)*	Dose	Indication	Route	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)

23b. Concomitant Medications being taken but NOT used to treat VAE: *(Doctor's Prescription page can be provided in lieu of completing this section)*	Dose	Indication	Route	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)

24. Relevant Medical History: Any other vaccination received within 4 weeks of the suspected vaccination, Illness at the time of vaccination, Allergies, Birth defects, Birth weight, Medical condition, history of adverse events following vaccination in the patient or siblings etc.

(Detailed Discharge Summary may be provided)

25. Reporting Doctor: *Signature: _____ * Date (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ *Contact No#_____	
TO BE COMPLETED BY GCCPL	
Date received (DD/MM/YYYY): _ _ / _ _ / _ _ _ _ Vaccine Adverse Event Number: _____ GCCPL Assessment of Causality: _____ GCCPL Assessment of Expectedness: _____ Date Document Source Verified: (DD/MM/YYYY): _ _ / _ _ /_ _ _ _ Does this Qualify for Expedited Reporting? YES/ NO FU required? : YES/ NO	Date Competent Authorities advised: DCGI_____EC_____ Assessment made by: Head Medical – Services GCCPL Assessor's Signature: _____ Date: _ _ /_ _ /_ _ _ _