BIO-MED
PRIVATE LIMITED

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Post Marketing Surveillance data for compilation of Periodic Safety Update Report for periodic and comprehensive assessment of safety of vaccines

Name of Executive: Mr._____State:_____Phone No.:_____Date:_____

Period covered		Area Visited	Feedback taken on following Vaccine (Tick)	Overall Safety Evaluation (Tick Severe/Adverse Drug Reaction Reported by doctors / dealers)	Sign
From	To		Poliomyelitis Vaccine LIVE (ORAL) Divalent (Bivalent/ bOPV)	Yes/No/NA	
			(Haemophilus type b conjugate Vaccine) PedaHib™	Yes/No/NA	
			(Typhoid Polysaccharide Vaccine) Bio Typh™	Yes/No/NA	
			PedaTyph™ (Typhoid Vi Conjugate vaccine)	Yes/No/NA	
			Bi Meningo™ (Meningococcal polysaccharide Vaccine (Group A & C)	Yes/No/NA	
			(Meningococcal Polysaccharide Vaccine (Group A,C,Y & W 135) QuadriMeningo™	Yes/No/NA	
			(Botulinum Toxin Type A for injection, Purified neurotoxin complex) Botogenie	Yes/No/NA	
			Rabies Vaccine Human SURE RAB™	Yes/No/NA	

Fortnightly enquiry for Post Marketing Surveillance for periodic and comprehensive assessment of safety of vaccines

S.No.	Checklist	Observation(*Tick √*)
1.0	Was the dosage and route of administration followed as per procedure?	Yes/No
2.0	Was presence of any foreign particulate matter observed detected visual inspection while administering the vaccine?	Yes/No
3.0	Was any variation observed in physical aspect of vaccines?	Yes/No
4.0	Were the precautions related to contra-indication of vaccines taken care off while administering?	Yes/No
5.0	Was any possible side effect observed? Like	
	a) Pain	Yes/No
	b) Pruritus/Itching	Yes/No
	c) Fever	Yes/No
	d) Redness	Yes/No
	e) headache	Yes/No
6.0	Was any drug reaction observed other than listed in side effects?	Yes/No

Conclusion (by Medical representative): Any drug reaction **reported/not reported** (*Tick √*).

Note: For Serious and Non serious Adverse events observed report the same into BM/PV/ANX/001B, In case of serious AEFI go through the FIR form BM/PV/ANX/001D need to be filled & submit is mandatory within defined time frame.

Remarks: _____

Medical representative (Sign/Date):	Reviewed by Pharmacovigilance Personnel (Sign/Date):