

Annexure –VII(b)

Details of Manufacturer whose licenses have been suspended /cancelled

S.No	Name of manufacturer	Name of product	Mfg. License No.	Action taken (Suspended/ Cancelled)	Date of Suspension/ Cancellation	Period of Suspension/ Cancellation
1.	M/s Shantha Biotechnics Private Limited., Survey No. 274 Athvelli Village Medchal Mandal 501401 Malkajgiri Telangana	For Domestic Purpose: 1. Hepatitis B Vaccine (rDNA) (Final Bulk Vaccine) I.P. Ready to fill (RTF) Bulk. 2. Hepatitis B vaccine (rDNA) I.P. 3. Diptheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) vaccine (Adsorbed) I.P. 4. Diptheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) vaccine (Adsorbed) Bulk I.P. 5. Diptheria, Tetanus, Pertussis vaccine (Adsorbed) I.P. [DTP Vaccine]. 6. Diptheria, Tetanus, Pertussis vaccine Bulk (Adsorbed) I.P. [DTP Vaccine Bulk]. 7. Haemophilus Type b Conjugate Vaccine I.P. 8. Diptheria, Tetanus, Pertussis (Whole Cell) Haemophilus Type b Conjugate Vaccine I.P. For Export Purpose:- 1. Hepatitis-B vaccine (rDNA) final bulk vaccine Ready to Fill (RTF) Bulk. 2. Hepatitis-B vaccine (rDNA) B.P. Brand Name: SHANVAC-B. 3. Adsorbed Diptheria, Tetanus Whole-cell Pertussis	01/RR/AP/97/V/R	Cancelled	16-04-2019	Permanent

Annexure –VII(b)

Details of Manufacturer whose licenses have been suspended /cancelled

		and Hepatitis–B [Recombinant] Vaccine Brand Name:SHANTETRA 4. Adsorbed Diphtheria, Tetanus and Pertussis Vaccine B.P. [DTP] Vaccine. Brand Name:SHANTRIP 5. Haemophilus Influenzae Typr b Conjugate Vaccine B.P/Ph.Eur Brand Name: SHAN-HIB. 6. Adsorbed Diphtheria, Tetanus Pertussis and Haemophilus Influenzae Type bConjugate VaccineBrand Name:SHAN HIB-DPT. 7. Adsorbed Diphtheria, Tetanus Pertussis and Haemophilus Influenzae Type bConjugate VaccineBrand Name:SHAN4				
2.	M/s Sanofi Healthcare India Pvt. Ltd. , Survey No. 274 Athvelli Village Medchal Mandal 501401 Malkajgiri Telangana	1. Adsorbed Tetanus Vaccine B.P. (5ml/10ml. multi dose vial) 2. Adsorbed Tetanus Vaccine B.P. (5ml/10ml. multi dose vial) 3. Adsorbed Tetanus Vaccine B.P. (5mlsingle dose vial) 4. Adsorbed Tetanus Vaccine Final Bulk Vaccine (Ready to Fill Bulk) (for multi dose presentation, stored in stainless steel (SS) 316 L Vessels) 5. Tetanus Vaccine (Adsorbed) Final Bulk Vaccine (Ready to Fill Bulk) (for single dose presentation, stored in	01/RR/AP/97/V/R	Cancelled	28-12-2021	Permanent

Annexure –VII(b)

Details of Manufacturer whose licenses have been suspended /cancelled

		stainless steel (SS) 316 L Vessels). 6. Tetanus Vaccine (Adsorbed) Final Bulk Vaccine (Ready to Fill Bulk) (for single dose presentation, stored in stainless steel (SS) 316 L Vessels). 7. Tetanus Vaccine (Adsorbed) Final Bulk Vaccine (Ready to Fill Bulk) (for multi dose presentation, stored in stainless steel (SS) 316 L Vessels). 8. Tetanus Vaccine (Adsorbed) IP (0.5 ml. single dose vial) 9. Tetanus Vaccine (Adsorbed) IP (0.5 ml. multi dose vial)				
3.	M/s Sanofi Healthcare India Pvt. Ltd. , Survey No. 274 Athvelli Village Medchal Mandal 501401 Malkajgiri Telangana	1. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA), <i>Haemophilus influenza</i> type B conjugate vaccine (Adsorbed) I.P. (Abbreviated as DTwP-HepB-Hib vaccine) in liquid vaccine form (0.5ml single dose and 5 ml Multi dose) 2. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA), <i>Haemophilus influenza</i> type B conjugate vaccine (Adsorbed) (Abbreviated as DTwP-HepB-Hib vaccine) in liquid vaccine form (Shan 5™) (0.5ml single dose and 5 ml multi dose) 3. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA), <i>Haemophilus influenza</i> Type B conjugate and Poliomyelitis (inactivated)	01/RR/AP/97/V/R & 01/MD/TS/2015/V/G	Cancelled	18.04.2023	Permanent

Annexure –VII(b)

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		vaccine (Adsorbed) (5ml 10 dose) 4. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA), <i>Haemophilus influenza</i> type B conjugate, Poliomyletis (inactivated) vaccine (adsorbed) (0.5ml single dose vial) 5. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA), <i>Haemophilus influenza</i> type B conjugate, poliomyletis (inactivated) vaccine (adsorbed) (Shan6™) (0.5ml single dose vial)				
4.	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet Mandal, Medchal District-500076, Telangana,	Typhoid Polysaccharide Vaccine IP (Typbar)	3/HD/P/96/V/R	Suspended	05-10-2023	15 Days
5.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar Pune-411028	1. BCG Vaccine & BCG for Immunotherapy (40mg & 80 mg) 2. Tetanus Antitoxin I.P. 1500 IU 3. Tetanus Antitoxin I.P. 10000 IU 3. Tetanus Antitoxin I.P. 20000 IU 4. Tetanus Antitoxin I.P. 50000 IU 5. Tetanus Antitoxin I.P. 25000 IU 6. Diphtheria Antitoxin I.P. 1000 IU 7. Diphtheria Antitoxin I.P. 2000 IU 8. Diphtheria Antitoxin I.P. 10000 IU 9. Snake Antivenom Serum I.P. (Freeze-Dried) Polyvalent Anti-Snake Venom Serum 10. Rabies Antiserum IP 1500 IU/5 ml 11. Bulk for Snake Antivenom	No.10	Cancelled	12-12-2023	Permanent

Annexure –VII(b)

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		Serum I.P. Polyvalent Anti-Snake Venom Serum 12. Bulk for Snake venom Anti- Sera Polyvalent Anti-Snake Venom Serum				
6.	M/s Biomed Pvt. Ltd. Ghaziabad	Meningococcal Polysaccharide Bivalent Vaccine IP (Group A & C)	05/LVP/Sera and Vaccines/2004	Suspended	19-04-2024	15 Days