

Annexure-IV(a):
Details of applications of manufacturing license of vaccines in Form 28D/28DA
and its regulatory status (Approved/Withdrawn) -April 2025 to June 2025

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1.	M/s MSD Pharmaceuticals Pvt. Ltd., at C/o M/s. M/s. Reenav Logistic Pvt. Ltd., H.No. 1124/E-1, Ground Floor, Rajlaxmi Hitech Park, NH3, Sonale Village, Bhiwandi-421302, Dist. Thane, Maharashtra	1. Human Papillomavirus 9-valent vaccine, Recombinant [Serotype: Type 6L1,11 L1, 16 L1, 18L1, 31L1, 33L1, 45L1, 52L1 & 58L1] 2. Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) vaccine Recombinant 3. Pneumococcal Polysaccharide Vaccine I.P. 4. Rotavirus Vaccine (Live Attenuated, Oral) I.P. 5. Varicella Vaccine, Live I.P.	03.04.2025	Nil
2.	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) (Domestic). Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) (Export). 3. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) ROTASIIL-LIQUID (Export) 4. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) (Export/WHO/UNICEF/PAHO) 5. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) (Export/WHO/UNICEF/PAHO) 6. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) ROTASIIL-Liquid (Export/WHO/UNICEF/PAHO) 7. ROTA VACCINE LIQUID CIPLA Liquid for Oral administration (Export)	03.04.2025	Nil
3.	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. Purified HPV Serotype 16 VLP Antigen (Domestic) 2. Purified HPV Serotype 16 VLP Antigen (Export)	03.04.2025	Nil

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4	M/s. Serawin Biologicals LLP situated at Sy. No. 84,89,90 and 91, Mutpoor Village, Kondurg Mandal, Ranga reddy District -509 207, Telangana State, India.	1. Diphtheria Antitoxin Plasma (Equine) 2. Rabies Antiserum Plasma (Equine) 3. Scorpion Venom Antiserum Plasma (Equine) 4. Snake Venom Antiserum Plasma (Equine) 5. Tetanus Antitoxin Plasma (Equine)	07.04.2025	Nil
5.	M/s Biological E. Limited, Plot No. 1, Biotech Park, Phase II, Kothur Village, Shameerpet, Medchal-Malkajgiri District- 500078, Telangana, India.	1. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (Ready to fill bulk) (for Domestic and Export Purpose). 2. Diphtheria and Tetanus Vaccine (Adsorbed Reduced Antigen(s) content) (Reduced Thiomersal) (Ready to fill bulk) (for Export Purpose). 3. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (For Domestic Purpose) 4. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (For Export Purpose) 5. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) (Reduced Thiomersal) (For Export Purpose) 6. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) (Reduced Thiomersal) BE Td (For Export Purpose)	08.04.2025	Nil
6.	M/s MSD Pharmaceuticals Pvt. Ltd., at C/o M/s. M/s S K Logistic, Gala No. 3A, 4A, 5 to 10, 11A & 12A, b-4, Citylink Warehousing Complex, S. No. 120-121, Mumbai Nashik Highway, Village- Vadapa Opp. Police Station, Bhiwandi-421302 District: Thane.	1. Human Papillomavirus 9-valent Vaccine, Recombinant [Serotypes: Type 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1] 2. Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) Vaccine Recombinant	21.04.2025	Nil

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		3. Pneumococcal Polysaccharide Vaccine I.P. 4. Rotavirus Vaccine (Live Attenuated, Oral) I.P. 5. Varicella Vaccine Live I.P.		
7	M/s GCBC Vaccines Private Limited, Survey No. 274, Athvelli Village, Medchal Mandal, Medchal - Malkajgiri District – 501401, Telangana, India	1. Cholera Vaccine (Inactivated, Oral) I.P. (Domestic) 2. Cholera Vaccine (Inactivated, Oral) B.P. (Export) 3. Inactivated Bivalent (O1 & O139) Oral Cholera Final Bulk Vaccine [Ready to Fill Bulk] (Domestic) 4. Inactivated Bivalent (O1 & O139) Oral Cholera Final Bulk Vaccine [Ready to Fill Bulk] (Export) 5. Inactivated Bivalent (O1 & O139) Oral Cholera Vaccine Bulk I.P. (Domestic) 6. Inactivated Bivalent (O1 & O139) Oral Cholera Vaccine Bulk B.P. (Export) 7. Tetanus Bulk Purified Toxoid I.P. (Domestic) 8. Tetanus Bulk Purified Toxoid B.P. (Export) 9. Diphtheria Bulk Purified Toxoid I.P. (Domestic) 10. Diphtheria Bulk Purified Toxoid B.P. (Export)	27.05.2025	Nil
8.	M/s Pfizer Limited, The Capital – A Wing, 1802, 18th Floor, Plot No. C-70, G-Block, Bandra-Kurla Complex, Bandra (East), Mumbai-400051 (India)	1. Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.P., 20-Valent (Prevenar 20)	28-05-2025	Nil
8	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India ,411028	Serogroup A, C, Y, W, X meningococcal polysaccharide conjugate vaccine (Export)	30.05.2025	Nil
9	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra, India ,412307	1. Purified HPV Serotype 6 VLP Antigen (Domestic) 2. Purified HPV Serotype 6 VLP Antigen (Export)	30.05.2025	Nil

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10	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra, India ,412307	1. Purified HPV Serotype 11 VLP Antigen (Domestic) 2. Purified HPV Serotype 11 VLP Antigen (Export)	30.05.2025	Nil
11	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra, India ,412307	1. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) (Domestic) 2. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) (Export) 3. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) [ROTASIIL-Liquid], (Export) 4. Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 4 ml - 2 dose (Glass Vial) (Export) 5. Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 4 ml - 2 dose (Glass Vial), ROTASIIL-Liquid (Export)	30.05.2025	Nil
12	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra, India ,412307	covid-19 vaccine, (recombinant), Multidose Vial 2.5 ml- 5 Dose (Export)	30.05.2025	Nil
13.	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra, India ,412307	1. Purified HPV Serotype 18 VLP Antigen (Domestic) 2. Purified HPV Serotype 18 VLP Antigen (Export)	25.06.2025	Nil

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14.	M/s Biological.E Limited (Sez), SY NO 549, 550, 552 TO 556, KOLTHUR VILLAGE, SHAMEERPET, Medchal, Telangana, India ,500101	1. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) I.P. (DTwP-rHepB-Hib) (For Domestic) 2. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed), (DTwP-rHepB-Hib) (For Export) 3. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) (DTwP-rHepB-Hib) ComBE Five (Liquid) - (For Export)	25.06.2025	Nil
15	M/s Biological.E Limited (Sez), SY NO 549, 550, 552 TO 556, KOLTHUR VILLAGE, SHAMEERPET, Medchal, Telangana, India ,500101	1. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) - Ready to Fill Bulk, (For Export) 2. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) I.P. (Ready to Fill Bulk) (For Domestic)	25.06.2025	Nil
16	M/s Panacea Biotech Ltd., Malpur, Baddi, Solan, Himachal Pradesh, India-173205	1. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP	25-06-2025	Nil