

Annexure-IV(a):

Details of applications of manufacturing license of vaccines in Form 28D/28DA and its regulatory status (Approved/Withdrawn) -July 2025 to September 2025

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1.	M/s Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	SARS-CoV-2rS JN.1 Variant Drug Substance (Export)	17.07.2025	Nil
2.	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Maharashtra, India, 411028	1. Influenza Vaccine (Human, Live Attenuated) I.P., Seasonal, Trivalent (Liquid) (Domestic). 2. Influenza Vaccine (Human, Live Attenuated) I.P., Seasonal, Trivalent (Liquid) (Export). 3. Influenza Vaccine (Human, Live Attenuated) I.P., Seasonal, Trivalent (Liquid) NASOVAC S3 (Export). 4. Influenza Vaccine (Human, Live Attenuated) Seasonal, Trivalent (Liquid) (Export).	17.07.2025	Nil
3.	M/s Zydus Lifescience Limited, Plot No. 23, 25/P, 37, 40/P 42 to 47, 49 & 50 Sarkhej-Bavla National Highway No. 8A, Opp. Ramdev Masala Village: Changodar, Taluka Sanand, Dist. Ahmedabad -382 213, State Gujarat.	1. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) Vial. WHO recommended strain for year 2025 2026 Northern Hemisphere for Influenza season (Domestic). 2. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) PFS. (Vaccine Combipack). WHO recommended strain for year 2025 2026 Northern Hemisphere for Influenza season (Domestic)	01.08.2025	Nil
4	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Maharashtra, India, 411028	Purified Rabies Antigen, Ravac Vaccine Ravac Vaccine (Export)	11.08.2025	Nil

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5.	M/s Biological E. Limited, (Vaccine) Plot No. 1, Biotech Park, Phase II, Kothur Village, Shameerpet, Medchal, Telangana, India ,500101	1. Tetanus Vaccine (Adsorbed) I.P (Domestic) 2. Tetanus Vaccine (Adsorbed) I.P (Export). 3. Adsorbed Tetanus Vaccine B.P. (Export). 4. Adsorbed Tetanus Vaccine B.P. BETT (Export).	11.08.2025	Nil
6.	M/s Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	COVID-19 Vaccine, Adjuvanted, NUVAXOVID (2025-2026 Formula) NUVAXOVID (Export).	11.08.2025	Nil
7	M/s Bharat Biotech International Limited, SY NO 230, 231 & 235, GENOME VALLEY, TURKAPALLY VILLAGE, Shamirpet Mandal, Medchal- Malkajgiri District, Telangana, India, 500078	Bivalent Poliomyelitis Vaccine Type 1 and 3, Live (Oral) IP. (Domestic)	29.09.2025	Nil
8	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India ,411028	1. Purified Tetanus Toxoid (Domestic). 2. Purified Tetanus Toxoid (Export)	29.09.2025	Nil
9	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India ,411028	1. Purified Diphtheria Toxoid (Domestic). 2. Purified Diphtheria Toxoid (Export)	29.09.2025	Nil