

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and its regulatory status (Approved/Withdrawn) -OCT. 2025 to DEC. 2025

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)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., 212/2, HADAPSAR, PUNE, Maharashtra, India, 411028	1. Rubella Vaccine (Live) I.P. (Domestic) 2. Rubella Vaccine (Live) I.P. (Brand Name: R-VAC® PFS) (Export) 3. Rubella Vaccine, Live B.P. (Export). 4. Rubella Vaccine, Live B.P. (Brand Name: R-VAC® PFS) (Export) 5. Rubella Vaccine, Live Attenuated (Freeze Dried) (Export) 6. Rubella Vaccine, Live, Attenuated (Freeze-Dried) (Brand Name: R-VAC® PFS) (Export) 7. Rubella Vaccine (Live) I.P. (Export)	03.11.20258	Nil
2.	M/s Bharat Biotech International Limited, Sy NOo230, 231 & 235, GENOME VALLEY, TURKAPALLY VILLAGE, Shamirpet Mandal, Medchal, Telangana, India, 500101	Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Domestic)	17.11.2025	Nil
3.	M/s Zydus Lifesciences Limited, Plot Survey No 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla National Highway No 8A, Opposite Ramdev Masala, Village - Changodar, Taluka - Sanand, District - Ahmedabad - 382213, State - Gujarat, India,	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Domestic). Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Vaccine Combipack) (Domestic). Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Brand Name ZyVac® MMR) (Export) Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Vaccine Combipack) (Brand Name ZyVac® MMR) (Export). Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried). (Export) Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried). (Vaccine Combipack). (Brand Name ZyVac® MMR) (Export)	15.12.2025	Nil

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and its regulatory status (Approved/Withdrawn) -OCT. 2025 to DEC. 2025

4.	M/s Serum Institute of INDIA Pvt. Ltd. S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune 411 028 PUNE, Pune, Maharashtra, India ,411028	Amendment in the address on Drug Manufacturing Licence No. in MLF28D2024MH000003 (Form-28D) of M/s Serum Institute of India Pvt. Ltd of the manufacturing premises	15.12.2025	Nil
----	--	--	------------	-----