File No: BIO/CT/25/000140
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division-Vaccine)

FDA Bhawan Kotla Road,
New Delhi-110002

From

The Drugs Controller General, India
Directorate General of Health Services,

To

M/s Serum Institute of India Pvt. Ltd.,
212/2 Off Soli Poonawalla Road. Hadapsar,
Pune, Maharashtra (India) -411028.

Subject: Permission for conducting a clinical trial titled "A Phase III, double-blind, randomized, active-controlled, multicentric clinical trial to evaluate the immunogenicity and safety of SIIPL's qHPV pvaccine (CERVAVAC®) administered intramuscularly in women aged 27 to 45 years as compared to Merck's HPV 6/11/16/18 vaccine (Gardasil®). (Protocol no.: SII-qHPV/IN-05 Version 2.0 dated 19-Dec-2025)".

Reference: Your Application No. BIO/CT04/FF/2025/52040 dated 17.09.2025 on the subject mentioned above.

Sir,

Please refer to your application No. BIO/CT04/FF/2025/52040 dated 17.09.2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase III Clinical Trial of "Quadrivalent Human Papillomavirus (Type 6, 11, 16, 18) Vaccine (Recombinant)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.02.26 14:56:21 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File No: BIO/CT/25/000140
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division-Vaccine)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune (India) - 411028 Telephone No.: 020-26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail: parag.nagarkar@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No. SII-qHPV/IN-05 Version 2.0 dated 19.12.2025 in the below mentioned clinical trial sites.

CT No.: CT- 02/2026

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Quadrivalent Human Papillomavirus (Type 6, 11, 16, 18) Vaccine (Recombinant)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Vaccines (Liquid)</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 mL suspension of injection contains:
<table>
<tr><th>Active ingredient</th><th>Quantity</th></tr>
<tr><td>Human Papillomavirus type 6 L1 protein</td><td>≥ 20 mcg</td></tr>
<tr><td>Human Papillomavirus type 11 L1 protein</td><td>≥ 40 mcg</td></tr>
<tr><td>Human Papillomavirus type 16 L1 protein</td><td>≥ 40 mcg</td></tr>
<tr><td>Human Papillomavirus type 18 L1 protein</td><td>≥ 20 mcg</td></tr>
<tr><td>Aluminium hydroxide (as AL+++)</td><td>≤1.25mg</td></tr>
</table>
*Produced from strain: Hansenula polymorpha</td></tr>
<tr><td>Presentation:</td><td>Single-dose and multidose (two-dose) vial (2R Type 1 glass vial).</td></tr>
<tr><td>Indication(s):</td><td>Vaccine is indicated for women of 27 through 45 years of age for the prevention of the following diseases caused by Human Papilloma virus types 6, 11, 16and 18</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	All India Institute of Medical Sciences, Department of Preventive Oncology, IRCH, Ansari Nagar, New Delhi-110029. India	Institute Ethics Committee, Room No. 102, 1st Floor, Old O.T Block, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029 ECR/538/Inst/DL/2014/RR-25	Dr. Neerja Bhatla
2	Christian Medical College, Department of Gynaecologic Oncology, Ida Scudder Road, Vellore-632004, Tamil Nadu. India	Institutional Review Board/Ethics Committee, Christian Medical College, Office of Research, Carman Block, Bagayam, Vellore-632002, Tamil Nadu. ECR/326/Inst/TN/2013/RR-24	Dr. Anitha Thomas
3	Tata Memorial Hospital, Department of Preventive Oncology, Main Building, 304, 3rd floor, Service Block, Dr. E. Borges Marg, Parel (E), Mumbai – 400012, Maharashtra. India	Institutional Ethics Committee, Tata Memorial Hospital, 3rd floor, Main Bldg, Dr. E. Borges Marg, Parel, Mumbai-400012, Maharashtra. ECR/414/Inst/MH/2013/RR-24	Dr. Sharmila Pimple

4	KEM Hospital Research Centre, Consultant Pediatrician & Neonatologist, Vadu Rural Health Program, Vadu Budruk, Taluka-Shirur, District Pune -412216, Maharashtra, India	KEM Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth, Pune-411011, Maharashtra. ECR/272/Inst/MH/2013/RR-22	Dr.Anand Kawade
5	Tata Medical Center, Preventive Oncology Department, 14 Major Arterial Road (EW), New Town, Rajarhat, Kolkata-700160	Tata Medical Center-Institutional Review Board (TMCIRB), 14, Major Arterial Road (EW) Newtown, Kolkata-700160 ECR/269/Inst/WB/2013/RR-24	Dr. Sonia Mathai
6	Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra, India.	Institutional Ethics Committee Poona Medical Research Foundation, E4-C to E4-F, 4th Floor, Fifth Avenue, Condominium, Dhole Patil Road, Pune - 411001, Maharashtra. ECR/24/Inst/MH/2013/RR-22	Dr. Smita Joshi

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled, titled “A Phase-III, double-blind, randomized, active-controlled, multicentric clinical trial to evaluate the immunogenicity and safety of SIIPL’s qHPV vaccine (CERVAVAC®) administered intramuscularly in women aged 27 to 45 years as compared to Merck’s HPV 6/11/16/18 vaccine (Gardasil®)” [Protocol number: SII-qHPV/IN-05, Version 2.0 dated 19.12.2025].
2. To submit Ethics Committee approval for Phase-III clinical trial.
3. Only CDL, Kasauli certified batch shall be used in proposed Phase-III clinical trial in India.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: