File No. ED/ECI/2025/01-June
Government of India,
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002.

Dated: 12 JUN 2026

Debarment order

Subject: Inspection of HCG Central Ethics Committee and clinical trial site, HCG Bangalore institute of Oncology. HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India –Reg.

References-.

1. Letter no. File No. ED/ECI/2025/01-June dated 02 July 2025 from DCGI, CDSCO, HQ, New Delhi
2. Show-cause notice issued by this office on 17.07.2025.

WHERAS, Risk Based inspection of the Central Ethics Committee and clinical trial site was conducted by a team comprises of officials of CDSCO,(HQ), New Delhi and Zonal office Bangalore, SLA, Bangalore along with subject expert on 03.07.2025 & 04.07.2025 at HCG- Bangalore institute of Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka – 560027 to assess the status of compliance of Ethics Committee formed under New Drugs and Clinical Trial Rules 2019 as per Risk Based approach.

AND WHEREAS, on the basis of recommendation of inspection team, the show-cause notice under Rule 30 (1) of NDCTR 2019 was issued by Central Licensing Authority on 17.07.2025 to Principal Investigator for submission of reply/clarification/compliance within 10 days.

AND WHEREAS, the response/clarification with respect to the show-cause notice received by this office on 26.07.2025 and on review of the submitted reply, it was noted that reply was not satisfactorily.

AND WHEREAS, you were given opportunity of personal hearing under Rule 30 (1) of NDCT Rule 2019 vide letter dated 01-09-2025 & accordingly you have presented your case on 12-09-2025 at 2:00 PM before Central Licensing Authority at First Floor, Conference hall, FDA Bhawan, Kotla Marg, ITO, Mandi house, New Delhi ,110002.

AND WHEREAS, upon perusal of the submitted reply and consideration of the submissions/clarification made during personal hearing, it has emerged that during EC meeting dated 25.09.2024 , you have signed a declaration to the effect that there is no conflict of interest, however you were Principal Investigator in the study as well as member of said EC, hence there was conflict of Interest, which you

failed to report. Further, you admitted that the Conflict of Interest declaration was inadvertently not obtained for Protocol No. 61186372NSC3002, in which you also acted Principal Investigator. Hence, you have violated Rule 7(10) and Rule 7(11) of the NDCT Rules, read with Para 2.4.2.6(2) of the Indian GCP Guidelines.

Hence as per power conferred by Rule 30.1(iv)) of the New Drugs and Clinical Trials Rules, 2019, and in the interest of public health & the protection of human participants in clinical trials/BA-BE studies, you are hereby debarred to undertake and conduct any new clinical trials or BA-BE study for a period of **06 months** from receipt of this order.

Also you are directed to actively supervise all ongoing clinical trials or BA-BE studies and submit monthly status report for safety and well-being of participant of the trials to CDSCO, HQ and Zonal Office, Bangalore.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority

To
Dr. Govind Babu (Principal Investigator),
M/s Healthcare Global Enterprises Ltd.,
No. 8, P Kalinga Rao Road, HCG Towers,
Sampangi Ram Nagar, Bengaluru-560027, Karnataka, India.

CC to:
1. Deputy Drugs Controller (India), CDSCO Zonal Office, Karnataka, Bangalore-560001 with direction for compliance of this order.

File No. ED/ECI/2025/01-June
Government of India,
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Division)

FDA Bhawan Kotla Road,
New Delhi - 110002.
Dated:

Debarment order 12 JUN 2026

Subject: Inspection of HCG Central Ethics Committee and clinical trial site, HCG Bangalore institute of Oncology. HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India –Reg.

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AND WHEREAS, the response/clarification with respect to the show-cause notice received by this office on 26.07.2025 and on review of the submitted reply, it was noted that reply was not satisfactorily.

AND WHEREAS, you were given opportunity of personal hearing under Rule 30 (1) of NDCT Rule 2019 vide letter dated 01-09-2025 & accordingly you have presented your case on 12-09-2025 at 2:00 PM before Central Licensing Authority at First Floor, Conference Hall, FDA Bhawan, Kotla Marg, ITO, Mandi house, New Delhi ,110002.

AND WHEREAS, upon perusal of the submitted reply and consideration of the submissions/clarification made during personal hearing, the following facts have emerged: -

1.You failed to report the Serious Adverse Events (SAEs), including death/injury cases, to the Central Licensing Authority (CLA) in the following instances, which is not in compliance with Rule 25(x), Rule 42(1) & 42(2)(ii), and Para 2(iii) of the Third Schedule of the NDCTR, 2019.

S. no.	Subject Id	Protocol No.	SAE Date	SAE not reported to CDSCO within timeline
1.	10-004	13Y-IN-JPEC	Injury on 19.08.2021	Fourteen days Causality assessment report not submitted to CLA.
2.	10-004	13Y-IN-JPEC	Death on 30.08.2021	Death was not reported to CLA
3.	E3503001	D910VC0001	Death on 08.06.2023	Death was not reported to CLA
4.	32001/S	AUR107-101	Death on 20.05.2025	Death was not reported to CLA

2 . For Subject ID-IN0420006, on review of casualty assessment report dated 02.09.2023, you have mentioned that the SAE was medically managed and the event Progressive liver disease was not related to Study drug. The patient completed the ongoing treatment. Since recovered and discharged in a stable condition and opined that there is no compensation for Clinical trial related to this SAE. However, on review of casualty assessment report, it was noted the subject participant was not recovered from the SAE since he was suffering from progressive liver disease with lungs Carcinoma however it was opined "as he has recovered and discharge from the hospital and inform the patient to retest the LFT after a week". Furthermore, the record of follow up and free medical management w.r.t. indoor treatment and retest the LFT report was not submitted. Hence, you failed to provided adequate medical management w.r.t. safety and wellbeing of the trial participants as per para no. 2 (ii) of third schedule and Rule 25 (xi) of NDCTR 2019.

3. You failed to submit the supporting documents with reason with respect to subject no. 10-011 and 10-013 which were drop out from the study after randomization/enrollment under study protocol no. 13Y-IN-JPEC.

4. You failed to provide clinical study report and safety follow up report of the terminated subjects after completion of Cycle (Cycle 6 day 28) under the protocol no. 13Y-IN-JPEC(b) in line with Second Schedule 1.1 (iv)(e) of NDCTR 2019.

5. You failed to report several protocol deviations under protocol no. NIVO.22.001 and SB27-3004 which were occurred in 2023 to EC & CLA immediately in line with para 1(vii) of Third Schedule of NDCTR.

6. You have stated that the subject id no. 10486 enrolled under protocol no. J2J-OX-JZLC experienced a Serious Adverse Event (SAE) from 01.02.2023 to 10.02.2023, and same SAE was intimated to EC and CLA on 17.02.2023.You failed to intimate initial SAE within 24 hrs of occurrence i.e. 01.02.2023, even proper management found not provided as the hospital did not advise any further treatment and asked subject to continue her existing medications (details of existing therapy not mentioned which subject was taking from treatment of Fatigue, breathless and cough. You have not submitted the discharge summary along with any supportive documents that the subject denied for admission in the hospital. Even for shifting subject from emergency to OPD not justified by you and the site has not taken follow up of the subject after discharge on 10.02.2023 and meanwhile the subject was died on 11.02.2023 and same SAE (death) was not reported within 24 hrs to EC and CLA in compliance with Rule 40 (1) & 42(i) and para no. 2 (ii & iii) of third schedule of NDCTR 2019.

AND THEREFORE, after consideration of the above facts and circumstances, it is concluded that you have neither reported serious adverse events including death to the CLA nor provided adequate medical care to the trial subjects, therefore you failed to perform your responsibilities as stated under Third Schedule Para no 3.2 of the New Drugs and Clinical Trials Rules, 2019.

Hence as per power conferred by Rule 30.1(iv)) of the New Drugs and Clinical Trials Rules, 2019, and in the interest of public health & the protection of human participants in clinical trials/BA-BE studies, you are hereby debarred to undertake and conduct any new clinical trial or BA-BE study for a period of **24 months** from receipt of this order.

Also you are directed to actively supervise all ongoing clinical trials or BA-BE studies and submit monthly status report for safety and well-being of participant of the trials to CDSCO, HQ and Zonal Office, Bangalore.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I) &
Central Licensing Authority

To
Dr. Satheesh C.T. (Principal Investigator),
M/s HCG- Bangalore institute of Oncology
HCG Towers, Tower-I P. Kalinga Rao Road,
Sampangiram Nagar Bangalore
Bengaluru(Bangalore) Urban Karnataka-560027.

CC to:

1. Deputy Drugs Controller (India), CDSCO Zonal Office, Karnataka, Bangalore-560001 with direction for compliance of this order.