



CENTRAL MEDICAL SERVICES SOCIETY

**2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021**

Email ID: gmproc1@cmss.gov.in; agmproc4@cmss.gov.in;

Ref: CMSS/QA/2024/003/544

Dated - 24/06/2024

To,

**M/s Bhat Bio-tech India (P) Ltd
No. 11A G Floor, 4th Cross, Veerasandra Industrial Area,
Electronics City, Bangalore- 560100,
Email- debhatbiotech@gmail.com,
M- 9880191998, 9538238671.**

Subject: Order for blacklisting to M/s Bhat Biotech India Pvt Ltd.

Dear Sir/Madam,

1. With reference to tender no. CMSS/PROC/2023-24/NACO/018, M/s Bhat Bio-Tech India Pvt Ltd had quoted 100% quantity of tendered quantity (3,44,640 Tests) for Schedule II i.e. Principle 2 Immunochromatography (Lateral Flow).
2. Purchase Order (PO) dated 01/12/2023 was issued to M/s Bhat Bio-Tech India Pvt Ltd for supply of 30% quantity of HIV Test Kit-3 Immunochromatography (Lateral Flow) being L2 bidder as per following details:

PO No.	Quantity (Tests)	Order Value (Rs.)	Funding Source	Delivery Schedule from LOA Date
CMSS/PROC/2023-24/NACO/018/106	1,03,392	9,11,917.4400	Domestic	Trance 1 within 120 days Trance 2 within 180 days Trance 3 within 270 days Trance 4 within 365 days

3. As per the provisions of tender document, Pre-delivery Inspection (PDI) of HIV Test Kit-3 for batch No. 16231114 was done on 22/12/2023 at the manufacturing premises of M/s Bhat Bio-Tech India Pvt Ltd i.e. "No. 11A G Floor, 4th Cross, Veerasandra Industrial Area, Electronics City, Bangalore- 560100" in the presence of CMSS officials, Programme Division and representative of supplier. The sample was collected and sent to the empanelment lab i.e. M/s National AIDS Research Institute (NARI) for quality analysis.

4. On 04/01/2024 test reports were received from NARI with following conclusion:

i. Kit showed only HIV-1 band for one HIV 1+2 panel member.



- ii. *The sensitivity for this kit is 93% and specificity is 100%. Hence, the kit does not meet the criteria of sensitivity as per CDSCO guidelines. Thus, the Kit (batch no. 16231114) is Not of Standard Quality.*
5. As per test report, batch no. 16231114 is declared as NSQ and same was communicated to M/s Bhat Bio-Tech India Pvt Ltd vide email dated 10/01/2024 to take Corrective & Preventive action and offer new batch of HIV Kit-3 as per tender terms & condition.
6. M/s Bhat Bio-Tech India Pvt Ltd offered new batch no. 16240106 of HIV Test Kit-3 and PDI was done on 29.01.2024. The sample was again sent to M/s National AIDS Research Institute (NARI) for quality analysis.
7. **On 12.02.2024 test reports of batch no. 16240106 were received from M/s NARI with following conclusion:**
- i. *The sensitivity for kit is Nil and specificity is Nil.*
- ii. *Single pack consisting of 50 tests showed 30% invalid test results and no control bands were observed in these defective test devices.*
- iii. *As per CDSCO guidelines, sensitivity and specificity was not calculated as one of the boxes of this batch showed 30% invalid test results making this batch invalid. Hence, the kit (batch no. 16240106) is Not of Standard Quality.*
8. As per test report, batch no. 16240106 is declared as NSQ and same was again communicated to the supplier vide email dated 13/02/2024 and requested to submit justification on this repetitive observation received from testing laboratory in quality of HIV Test Kit-3.
9. Vide email dated 14/02/2024, M/s Bhat Bio-Tech India Pvt Ltd submitted their justification and challenge the test report and request to retest the same batch from another lab. Vide email dated 15.02.2024, CMSS informed to the supplier that, "Testing of Control samples shall be further done by the lab empaneled by CMSS. Testing from another lab is not possible. Please note that in case the results of control batch also found to be Not of Standard Quality then further action shall be taken as per tender conditions. You are requested to give your consent on the testing of Control samples of batch to process your request further."
10. Vide email dated 16.02.2024, M/s Bhat Biotech India Pvt Ltd submitted their consent with mentioning that, "We give our consent to re test the control samples at the lab empaneled by CMSS. Also, we request and assume that the testing center will follow the right protocol or procedure for testing and interpret the results as mentioned in the pack inserts provided."
11. **CMSS sent the control sample of batch no. 16240106 to empaneled lab i.e. NICED Kolkata and test reports were received on 05/03/2024 with following conclusion:**
- i. *No control bands were visible in three boxes.*
- ii. *Eleven (11) devices were missing in a single box. Instead of 50 devices, 39 devices have been received in that box.*
- iii. *A single box containing 50 devices showed more than 30% invalid test results.*
- iv. *The sensitivity and specificity for this kit cannot be calculated as one of the boxes of this batch showed more than 30% invalid test results and making this batch invalid. Hence the kit (batch no.:16240106) is Not of Standard Quality.*



12. Form above, it is concluded that during quality testing, two batches (batch no. 16231114 & 1624016) offered by the supplier were found "Not of Standard Quality" by the empaneled lab of CMSS. Even Control sample of batch no. 1624016 were also tested and found "Not of Standard Quality". The supplier failed to deliver the items as per Purchase Order as well as comply to the tender terms & condition after three rounds of quality testing by the empanelled lab.

13. A show-cause notice was issued on dated 06/03/2024 by CMSS to M/s Bhat Biotech India Pvt Ltd to provide detailed explanation till 11/03/2024 to take appropriate actions as per tender clause no. 5 (viii, x, xi), 16.7, 16.8 & 20 of tender document to cancel the Purchase Order at the risk and cost of the defaulting vendor, to forfeit the performance security and debar/blacklist the supplier. The tender clause no. 5 (viii), 16.7 & 20 of tender document reproduced below:

"5 (viii.) TERMINATION FOR DEFAULT:

1. *The purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default, sent to the supplier, terminate this contract in whole or in part.*

(a) If the supplier fails to deliver any or all of the goods within the time period(s) specified in the contract, or any extension thereof granted by the purchaser.

(b) If the supplier fails to perform any other obligation(s) under the contract, and

(c) If the supplier, in either of the above circumstances, does not remedy his failure within a period of 15 days (or such longer period as the purchaser may authorize in writing) after receipt of the default notice from the purchaser.

2. *In the event the purchaser terminates the contract in whole or in part, pursuant to above the purchaser may procure; upon such terms and in such manner, as it deems appropriate, tendered goods undelivered and the supplier shall be liable to the purchaser for any excess cost for such similar goods. However, the supplier shall continue performance of the contract to the extent not terminated.*

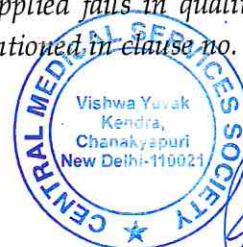
(x) SET OFF:

Any sum of money due and payable to the supplier (including security deposit refundable to him) under this contract may be appropriated by the purchaser and set off the same against any claim of the purchaser for payment of a sum of money arising out of this contract or under any other contract made by the supplier with the Purchaser.

(xi) Purchaser reserves the right to debar/ blacklist a bidder for a suitable period in case he fails to honour his bid/contract without sufficient grounds.

16.7 *At any of Inspection/testing stage, samples which do not meet quality requirement/specifications shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods and the cost of entire batch paid will be recovered whether consumed fully/ partially. Besides action may also be initiated for debarring/blacklisting against supplier for suitable period.*

16.8 *In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of testing stages (as mentioned in clause no. 16.3), depending upon*



the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either:

(i) Ask the supplier to replace the entire quantity of relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or

(ii) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

(iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition to forfeiture of Performance Security Deposit.

(iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

(v) The decision of the CMSS or any officer authorized by CMSS, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding.

20. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF DELAYS/ DEFAULT/TERMINATION/PART CANCELLATION/SHORT CLOSURE:

20.1 If the samples do not conform to tender specifications, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the receipt of the letter from the CMSS. Such stock shall be taken back at the expense of the Tenderer. The CMSS has the right to destroy such "NOT OF STANDARD QUALITY DRUGS" if the Tenderer does not take back the goods within the stipulated time. The CMSS will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" after the expiry of 30 days mentioned above without further notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value of the drugs rejected till such time stipulated.

20.2 The CMSS will be at liberty to terminate, without assigning any reasons thereof, the contract either wholly or in part or short closed on 30 days' notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Security Deposit and purchaser reserves the right to purchase balance- unsupplied item at the risk and cost of the defaulting vendor.

20.3 For infringement of the stipulations of the contract, for non-performance/ compliance of contractual terms or for other justifiable reasons, the contract may be terminated either wholly, or in part or short closed. by the CMSS and the Tenderer shall be liable to pay for all losses sustained by the CMSS in consequence of the termination which may be recovered personally from the Tenderer or from his properties, as per rules besides forfeiture of Security Deposit.

20.4 In the event of making Alternative Purchase, as specified in in Clause 13(f), Clause 14.2(a), Clause 16.8 and other clauses herein, penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the CMSS, in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

20.5 In all the above conditions, the decision of the CMSS shall be final and binding."



A handwritten signature in blue ink, appearing to be a stylized name or initials.

14. M/s Bhat Bio-Tech India Pvt Ltd submitted their reply vide email dated 11/03/2024 and which has been examined by the competent authority. After that, a letter (No. CMSS/QA/2024/003) on 15/05/2024 was issued by CMSS with following decisions:

- i. As per above referred tender document clause no. of tender ref no. CMSS/PROC/2023-24/NACO/018, the Purchase Order (PO) No. CMSS/PROC/2023-24/NACO/018/106 dated 01/12/2023 (No. 10282300147/PDI/Domestic Fund-DF) issued to M/s Bhat Biotech India Pvt Ltd for the supply of HIV Test Kit-3 Immunochromatography (Lateral Flow) is hereby cancelled at the risk and cost of defaulting supplier i.e. M/s Bhat Biotech India Pvt Ltd.
- ii. The performance security of Rs. 27,360/- (BG No. 0360NDLG00004124, Bank Name- ICICI Bank, Issue Date- 27/10/2023, Validity- 30/04/2027) submitted by M/s Bhat Biotech India Pvt Ltd for the said item shall also be forfeited in accordance with the terms & conditions of the contract.

15. Further, CMSS provided one more opportunity to M/s Bhat Biotech India Pvt Ltd to submit their reply regarding debarring/blacklisting and issued 2nd Show Cause Notice on 12/06/2024 vide letter no. CMSS/QA/2024/003/527.

16. M/s Bhat Bio-Tech India Pvt Ltd submitted their reply vide email dated 17/06/2024 and which has been examined by the competent authority and following decisions have been taken with immediate effect:

- i. M/s Bhat Biotech India Pvt Ltd is hereby blacklisted for one year i.e. from 24/06/2024 to 23/06/2025 to participate in future tender of Central Medical Services Society (CMSS) for item name HIV Test Kit [Immunochromatography (Lateral Flow)] with immediate effect.

With regards,


General Manager (Procurement)

Copy to: (i). Deputy Secretary (EPW), MoHFW

(ii). All Programme Division (NACO/NTEP/NVHCP/FP/CHP/NCVBDC/UIP) of MoHFW

(iii). All GM & AGM, CMSS



