

I/544097/2024



**OFFICE OF THE MANAGING DIRECTOR
ASSAM MEDICAL SERVICES CORPORATION LIMITED
Central Drug Ware House Campus, Patherquery, Narengi, Guwahati, Assam-781026
Email id: md-amscl@assam.gov.in**

No. 361274

From:

Dr Robin Kumar, IPS
Managing Director,
Assam Medical Services Corporation Limited.

To:

M/s Unicare India Ltd
Unit 1, C-21, 22, 23, Sector-3, Noida
Dist.: Gautam Budh Nagar (UP).

Sub: Product debarment notice of "Calcium (500mg) and Vitamin D3(250IU) Tablets

Ref:

1. Purchase Order no.- NHM-43017/ 49 /2022-PROC-NHM /ECF-229564/2020102381657, Dated:20.01.2023.
2. Test report vide no. GUW/LS/2023-24/1171 Date: 18.12.2023.
3. Notice letter no. I/378693/2023 dated 21.12.2023 for replacement of NSQ batches of Calcium (500mg) and Vitamin D3(250IU) Tablets
4. Test report vide no. GUW/LS/2023-24/1315 Date: 02.01.2024.
5. Notice letter no. I/404334/2024 dated 10.01.2024 for replacement of NSQ batches of Calcium (500mg) and Vitamin D3(250IU) Tablets
6. Show Cause notice no. I/484717/2024 dated 04.03.2024 & I/484719/2024 dated 04.03.2024.
7. Test Report no. GUW/LS/2023-24/1825 dated 14.03.2024 & letter of Drug Inspector dated 16.03.2024 & shared vide email dated 18.04.2024
8. Your email dated 10.04.2024 & 25.04.2024
9. Tender no: - NHM & AMSCL/PROC/RC-DRUGS/NEW EDL/ [NHM/18011/17/2020-PROC-NHM/ECF-142502/19212].
10. Final Show Cause notice regarding Products debarment issued on 08.04.2024

Sir/Madam,

With reference to the subject mentioned above, it is to inform you that your organization has taken part in the referred tender (at above pt.9) and was selected as L1 bidder for Calcium (500mg) and Vitamin D3(250IU) Tablets. Accordingly, you were awarded Letter of Intent (LOI) & you have entered Rate of Contract (RC) with NHM Assam & AMSCL Assam. Accordingly, Purchase Order (referred at Point 1) were issued on 20.01.2023 for supply of Calcium (500mg) and Vitamin D3(250IU) Tablets.

- A PO NHM-43017/49/2022-PROC-NHM/ECF-229564/2020102381657 dated 20.01.2023, were issued to you for supply of Calcium (500mg) and Vitamin D3(250IU) Tablets.
- Subsequently, your supplied item "Calcium (500mg) and Vitamin D3(250IU) Tablets having batch no. UDT10673, Mfg. date: Feb-2023 & Exp date: -July-2024, Batch no. UDT10704, Mfg. date: March-2023 and Exp date: Aug-2024 and Batch no. UDT10723, Mfg. date:- March-2023 & Exp date- Aug -2024 have been declared as "Not of Standard Quality-NSQ" as per test report at Pt.2,4 & Pt.7 above.

AMSC-QC/10/2023-QLT-AMSC-Assam Medical Services Corporation Limited

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- Therefore, a final show cause notice has been issued on 08.04.2024 to your organization as to why aforesaid product should not be debarred as per the clauses mentioned in the tender condition and penal provision as per tender should not be implemented.
- A reply has been received through email on dated 10.04.2024 and 25.04.2024, which is not satisfactory.
- Also, it is to be mentioned that there are three batches of the aforesaid product have been declared as "Not of Standard Quality" by the Government laboratory i.e., RDTL, Guwahati.

AMSC authority found that said drug is essential in nature for needy patients getting treatment in Govt. Health Institutions. Whereas it is found that three batches of a particular item supplied by your firm failed in the Quality test.

Hence below penal action as per tender clause at Pt. 5.18 (under reference at pt.9) "Penalty/debarment in Case of Quality Failure", will be imposed on your company. (As stated below)

A. Tender clause no. 5.18: Penalty in Case of Quality

- 5.18.1 Government of Assam is mandated to provide quality medicines to all the citizens coming to public health facility for treatment with an objective to give utmost priority to patient safety. Hence any deviation or non-conformity to patient safety will be taken seriously. The suppliers are required to supply drug items of high-quality standard as per prescribed specification and applicable statutory standards so that the efficacy and effectiveness of the drug items remain intact throughout the lifecycle of the drug. The Purchaser shall draw or cause to draw random sample at any time during the shelf life of the product and send it for quality testing to empaneled NABL accredited labs for quality testing.
- 5.18.2 If the sample drawn from any supplied drug fails the quality test (by any Government or empaneled NABL accredited lab by the Tender Inviting Authority) or the sample doesn't conform to the statutory standards and specifications, then the supplier will be liable for penalty (Administrative & Financial) based on the nature and degree of default as given below.

Therefore, as per tender clause at Pt. 5.18 "Penalty/debarment in Case of Quality Failure", your company has to withdraw the entire unconsumed batches of item from the delivery destinations, within 30 days of intimation, at your own cost and shall not be entitled for any payment for the quantity supplied for that particular batches which were declared as NSQ subsequently, irrespective of the fact that the item has been utilized partially.

In case one batch of a particular item supplied by a Firm failed the quality test: -(the quality test to be done by any Government or empaneled NABL accredited lab).

- Penalty for delay in withdrawal of NSQ items:** In case the supplier fails to withdraw the NSQ items from respective facilities or stores wherever it is lying, within 30 days of notice period, shall be liable for demurrage and charge of 2% of the total value of NSQ items supplied for each week of delay (delay period shall start after expiry of 30 days of notice period) up to a maximum of four weeks, failing which authority shall take steps for destruction or safe disposal procedure of the NSQ items and recover the expenses from the supplier in addition to demurrage charges.
- Penalty for delay in replacement of NSQ items:** Replace entire quantity of items supplied from that batch, even if consumed partially, within 30 days of intimation of such failure with a penalty of 2% of the value of the item supplied from that batch for each week of delay or part thereof (delay period shall start after expiry of 30 days of notice period) up to a maximum of 5 weeks.
- Penalty for non-supply or non-replacement:** If the supplier fails to replace the entire batch of NSQ items supplied within 30 days of notice period or even within the penal period of 5 weeks post the notice period, the rate contract shall be terminated and supplier shall be debarred for 3

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years from participating in any tender issued by the Tender Inviting Authority (TIA) for that item or product.

In case three batches of a particular item supplied by a Firm failed the quality test: -(the quality test to be done by any Government or empaneled NABL accredited lab).

- i. **Product debarment:** In addition to above penalties, the Firm shall be debarred from participation in any tender floated by the TIA for three years from the date of issue of letter of debarment for that item.

Hence, in the greater public & patient interest, your company "M/s Unicare India Ltd" is hereby debarred for three years from participating in any tender issued by the Tender Inviting Authority (TIA) for the product Calcium (500mg) and Vitamin D3(250IU) Tablets, as per referred tender clause 5.18, because three batches of the ordered drug i.e., Calcium (500mg) and Vitamin D3(250IU) Tablets have declared as Not of Standard Quality by the Government laboratory i.e., RDTL, Guwahati.

In addition to the product debarment the performance security deposited by the supplier for that particular product shall be forfeited and apportioned towards financial penalty.

Signed by

Robin Kumar

Date: 04.05.2024 13:39:33
Managing Director, AMSCL, Assam

ECF. No. 361274

Copy to the:

1. Commissioner & Secretary to the Govt of Assam, Health & Family Welfare Dept. for favour of kind information.
2. Mission Director, NHM, Assam for kind information.
3. Director of Medical Education, Assam for information.
4. Director of Health Services, Assam for information.
5. Drugs Controller of Assam for information.
6. Assistant Drugs Controller (India), O/o The Assistant Drugs Controller (India), CDSCO Sub- Zone, Guwahati for information.
7. Sr. Finance Controller, AMSCL. He is requested to initiate all financial penalties as proposed above.
8. Sr. Manager (IT), AMSCL for upload the debarment notice in the website.
9. P.S to the Hon'ble Minister, Health & FW for kind information to the hon'ble minister.

E-Signed
Managing Director, AMSCL

