



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

ECF No. 509167

From:

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

To:

Mercury Laboratories Limited
18 Shreeji Bhuvan 51 Mangaldas Road
Mumbai-400002

Sub: - Product Debarment notice due to quality failure of three batches of Levocetirizine Dihydrochloride (A) Plus Montelukast(B) Tablet IP (A) 5mg Plus (B)10 mg manufactured by M/s Mercury Laboratories Limited -reg

Ref:

1. Tender No. NHM &AMSCL/PROC/RC-DRUGS/NEW EDL/ [NHM / 18017 /31/2019- PROC-NHM/8328 DT 05072019, NHM/18011/17/2020-PROC-NHM/ECF- 142502/19212], Corrigendum No. NHM/18017/31/2019-PROC- NHM/18485, Date: 16.10.2019.
2. Notice No. NHM-18017/16/2018-PROC-NHM/ECF:70586/8266 Date: 03.08.2022
3. Notice No. I/514744/2024 Date: 31.03.2024.
4. Govt Analyst RDTL, Guwahati Test report (in FORM -13) vide no. GUW/LS/2024-25/491 Date: 26.06.2024.
5. Purchase Order no.-NHM-18011/ 41/ 2022-PROC-NHM/ECF: 206559/ 2020102381065 dated 19.06.2022.
6. Purchase Order no.-NHM-18011/ 41/ 2022-PROC-NHM/ECF: 206559/ 2020102381453 dated 29.09.2022
7. Purchase Order no.-NHM-18011/ 46/ 2022-PROC-NHM/ECF: 209129/ 2020102381265 dated 28.06.2022
8. Purchase Order no.-NHM-18011/ 46/ 2022-PROC-NHM/ECF: 209129/ 2020102381338 dated 29.09.2022.
9. Notice E file no. 509167 dated 05.07.2024

Sir/Madam,

With reference to the subject cited above, it is to inform you that, AMSCL had issued notice on dated 03.08.2022 and 31.03.2024 due to declaration of **NSQ batches of Levocetirizine Dihydrochloride (A) Plus Montelukast(B) Tablet IP (A) 5mg Plus (B)10 mg having Batch no. 21112704 and 23112703**, manufactured by M/s Mercury Laboratories Limited respectively (reference at Pt. 2, 3).

Also, it is to be mentioned that another batch of Levocetirizine Dihydrochloride (A) Plus Montelukast(B) Tablet IP (A) 5mg Plus (B)10 mg having **Batch no. 23112701** supplied against the P.O. 2020102381065, 2020102381453, 2020102381265 & 2020102381338 has been declared as '**Not of Standard Quality**' as per test report under reference placed at Pt. 4.

AMSCL has issued a show cause notice to M/s Mercury Laboratories Limited regarding the product debarment due to the quality failure of three batches of Levocetirizine Dihydrochloride (A) Plus

Montelukast (B) Tablets IP (A) 5mg Plus (B) 10mg on dated 05.07.2024, & respectively a response has been received from firm; whereas, the clarification submitted was not satisfactory. Hence, M/s Mercury Laboratories Limited is liable to be penalized as per the tender terms and conditions.

AMSC authority found that said drug is essential in nature for needy patients getting treatment in Govt. Health Institutions. Whereas, non-supply of the same resulted non-availability & hindrance in public service, especially during the treatment of patient community at public health facilities and resulted increase in out-of-pocket expenditure.

Hence below penal action as per tender clause at Pt. 5.18 (under reference at pt.1) "Penalty/debarment in Case of Quality Failure", will be imposed on your company. (As stated below):-

"Penalty/debarment in Case of Quality Failure" as per tender clause at Pt. 5.18 (under reference at pt.1) are-

1. In case of one batch of a particular item supplied by a firm failed the quality test (The quality test to be done by Government or empaneled NABL accredited laboratory)

- The supplier has to withdraw entire batch of the item remained unconsumed within 30 days of intimation of the failure at its own cost.
- The supplier shall not be entitled for any payment for the quantity supplied from that particular batch which was declared NSQ subsequently, irrespective of the fact that the items have been consumed partially.
- **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 years from participating in any tender issued by the Tender Inviting Authority (TIA) for that item or product.

2. In case of three batches of a particular item supplied by a firm failed the quality test (The quality test to be done by Government or empaneled NABL accredited laboratory)

- **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.

3. Where the supplier has rate contract for three (3) or more items and debarred for a minimum of three items.

- **Firm debarment:** The firm shall be blacklisted or debarred from participating in any tender for any item (s) issued by the TIA for 3 (Three) years from the date of information.
- **Forfeiture of Performance Security:** In addition to firm debarment the entire performance security deposited by the supplier shall be forfeited and apportioned towards financial penalty.

Hence, in the greater public & patient interest, your company "M/s Mercury Laboratories Limited" is hereby debarred for 3 years from participating in any tender issued by the Tender Inviting Authority (TIA) for that product, as per referred tender clause 5.18, from date of issuance of this letter.

This is for favour of your information.

Yours Sincerely

Signed by

Robin Kumar

Date: 15-07-2024 16:10:59

Managing Director, AMSCL

ECF No. 509167

Copy to the: -

1. Commissioner & Secretary to the Govt of Assam, Health & Family Welfare Dept. for favor of kind information.
2. Mission Director, NHM, Assam for kind information.
3. Director of Health Services, Assam for information.
4. Drugs Controller of Assam for information and he is requested to check more batches of the said item and send for necessary analytical testing on priority basis.
5. Assistant Drugs Controller (India), O/o The Assistant Drugs Controller (India), CDSCO Sub-Zone, Guwahati for information and necessary action.
6. DDSM, i/c DDWH, All Districts/M. O i/c CMS, All Medical College Hospital for information and necessary action.
7. Sr. Finance Controller, AMSCL. He is requested to initiate all financial penalties as proposed above.
8. Sr. Manager (IT), AMSCL for uploading 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