



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

No. 4813 /OSMC/QA/1694/2016

Date : 05.05.2017

ORDER

M/s. Haseeb Pharmaceuticals Pvt. Ltd. (HPPL), Plot No. F 9/15, MIDC, Nagpur - 440016, Maharashtra, was placed with orders to supply 18408 X 20 & 54880 X 20 bottles of Inj. Compound Sodium Lactate I.P. (Ringer's Lactate) vide Purchase Order No. CR15473 dt.16.11.2015 & CR15781 dtd.22.01.2016 respectively. The firm supplied the drugs in a number of batches, out of which, two (02) batches i.e. i) Batch no. F151139, Mfg. Dt.11/2015, Exp. Dt.10/2017, which was drawn by the Drugs Inspector, Cuttack-II Range for test & analysis has been declared as "Not of Standard Quality" by Govt. Analyst, State Drug Testing & Research Laboratory (SDT&RL), Odisha as the sample is not of IP Standard in respect of Bacterial Endotoxin Test (BET), content of potassium and total chlorides and ii) Batch no. F16233, Mfg. Dt.02/2016, Exp. Dt.01/2018, which was drawn by the Drugs Inspector, Ganjam-II Range has also been declared as "Not of Standard Quality" by Govt. Analyst, SDT&RL, Odisha as the sample does not conform to IP Standard in respect of Sterility Test. The Test Reports of the Govt. Analyst was intimated by the Drugs Controller, Odisha to OSMCL vide his letter no. 9285 dtd.20.10.2016.

Based on such communication and test reports received, HPPL was issued show cause notice as per Purchase Order Clause 6(g)(ii) and Bid Condition 6.39.8.1(ii) of Bid Reference No. OSMCL/2015-16/DRUGS-DHS-Cat-II/03 seeking explanation as to why it shall not be blacklisted/debarred from supplying the item 'Inj. Compound Sodium Lactate I.P. (Ringer's Lactate) vide this office letter no. 9456/OSMC/QA/1694/2016 Dt.24.10.2016.

In reply to show cause notice dtd.24.10.2016, it has represented not to initiate any action against them on the basis of an inconclusive report and to wait for the report from the Central Drugs Laboratory (CDL), Kolkata as it has assailed/challenged/controverted the Test Report of the Govt. Analyst, SDT&RL, Odisha to CDL, Kolkata within 28 days from the date of receipt.

The firm requested for personal hearing, which was allowed and accordingly the authorised signatory of the firm appeared before the Managing Director on 03.01.2017 and submitted copy of documents to prove prima facie that it has taken steps to challenge the test reports of Govt. Analyst, SDT&RL before the concerned Drugs Inspectors and for retesting the sample at appellate laboratory i.e. CDL, Kolkata.

I have gone through the representation of HPPL and is of the considered opinion that as the matter stands today, two batches of the subject drug have been declared as Not of Standard Quality by Govt. Analyst, SDT&RL, Bhubaneswar. Quality of intravenous fluid of this nature cannot be compromised under any circumstances. The corporation cannot afford to wait for indefinite period for any other report to be produced.

Ravindra

(P.T.O.)

As per bid condition No. 6.31.7 of the bid document reference No. OSMCL/2015-2016/DRUGS-DHS-Cat-II/03 the reports of State Drug Testing & Research Laboratory, Odisha will have overriding effect. Accordingly Letter of Intent (L.O.I) was issued to M/s. Haseeb Pharmaceuticals Pvt. Ltd. and the same was agreed upon and accordingly agreement dtd.18.08.2015 signed with the said firm.

Therefore, as per the terms and conditions of the Purchase Order Clause 6(g)(ii) & 6(e) and Bid condition no. 6.39.8.1(ii) & 6.31.7 of Bid Reference No. OSMCL/2015-2016/DRUGS-DHS-Cat-II/03, M/s. Haseeb Pharmaceuticals Pvt. Ltd. is hereby blacklisted/debarred for the item i.e. Inj. Compound Sodium Lactate I.P. (Ringer's Lactate) for a successive period of three years from the date of issue of this order.

The performance security/ Bank guarantee/ EMD submitted by the firm for the said item is hereby forfeited and the firm shall not be allowed to supply and participate in the tender process of OSMCL for the said item.

Ravindra
R.P.Singh, I.A.S.
05/05/17
Managing Director, OSMCL

Memo No. 4814 Dt. 05.05.2017

Copy forwarded to M/s. Haseeb Pharmaceuticals Pvt. Ltd., Plot No. F 9/15, MIDC, Nagpur - 440016, Maharashtra, for information.

Ravindra
Managing Director
OSMCL

Memo No. 4815 Dt. 05.05.2017

Copy forwarded to the Commissioner, Food and Drugs Admn., 341, Bandra Kurla Complex, Opp. RBI Building, Bandra (East), Mumbai- 400051 for information and necessary action.

Ravindra
Managing Director
OSMCL

Memo No. 4816 Dt. 05.05.2017

Copy forwarded to the Drugs Controller, Odisha for information and necessary action with reference to his letter no. 9285 dtd.20.10.2016.

Ravindra
Managing Director
OSMCL

Memo No. 4817 Dt. 05.05.2017

Copy forwarded to the DHS, Odisha/ DMET, Odisha for information and necessary action.

Ravindra
Managing Director
OSMCL

Memo No. 4818 Dt. 05.05.2017

Copy submitted to the Commissioner-cum-Secretary to Govt., H & FW Dept. Odisha, for favour of kind information.

Ravindra
Managing Director
OSMCL

Memo No. 4819 Dt. 05.05.2017

Copy forwarded to all the divisions of OSMC for information and necessary action.

Ravindra
Managing Director
OSMCL