



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

Order No. : 15282/OSMCL/QA/1216/2018

Date : 03.10.2018

ORDER

M/s. Zee Laboratories Ltd., Uchani G.T. Road, Karnal, Haryana – 132001 was placed with orders to supply Paracetamol Paediatric Oral Suspension IP (125mg/5ml) vide Purchase Order No. CR17955 dtd.19.01.2018. The firm supplied the drug in a number of batches, out of which two (02) number of batches have been declared as “Not of Standard Quality” (NSQ) by two out of three approved NABL accredited laboratories empanelled by Odisha State Medical Corporation Ltd. (OSMCL), which were communicated to the supplier by enclosing the copies of test reports vide this Office letter No. 11709 dtd.30.07.2018 under intimation to the State Drugs Controlling Authority, Nagar Panchayat Bhawan, Sai Road, Baddi, Dist-Solan, Pin-173205 (HP) vide Memo No. 11711 dtd.30.07.2018.

The details of batches of subject drug and the reason for declaring the said batches as NSQ are mentioned below.

Sl. No.	Batch No.	Mfg. Dt.	Exp. Dt.	Reason for declaring NSQ	Mfd. By
01	618-156	02/2018	01/2020	Sample of the batch does not comply w.r.t Assay Test as per IP	M/s. Zee Laboratories Ltd., Behind 47, Industrial Area, Paonta Sahib – 173025
02	618-174	02/2018	01/2020	Sample of the batch does not comply w.r.t Assay Test as per IP	

In view of the above M/s. Zee Laboratories Ltd. was issued with Show Cause Notice vide this office letter No. 11898 dtd.03.08.2018 seeking explanation within seven (07) days of receipt of the letter as to why it shall not be derecognised/blacklisted for the item Paracetamol Paediatric Oral Suspension IP (125mg/5ml) for a period of three (03) successive years in accordance with PO Clause No. 5(h)(ii) read with Bid Condition No. 6.39.8.1(ii) of Bid Reference No. OSMCL/2017-18/DRUGS-DHS/02.

In response to the Show Cause Notice dtd.03.08.2018, the Noticee-firm vide letter dtd.07.08.2018 & 18.08.2018 replied that they have got the samples of the above mentioned batches tested by two NABL labs and the results are found to be satisfactory. Further, the test report from another independent NABL laboratory is also awaited and shall be submitted immediately after receipt. The firm has also intimated that the State Drug Licensing Authority, Himachal Pradesh (HP) is also investigating the matter and the results of the investigation is awaited. The firm has requested to wait for the outcome of the investigation of the Drugs Controller, HP before taking any decision in the matter.

(P.T.O)

In order to avoid such kind of conflicting claims it was made clear in Condition No. 6.39.8.1(ii) of the Notice Inviting Tender (N.I.T) as well as in Clause No. 5(h)(ii) of the Purchase Order "In case of Not of Standard Quality (NSQ) report of the sample from the approved NABL Accredited Laboratory empanelled by OSMCL, two (02) other portions of the sample shall be sent to two (02) different laboratories empanelled by OSMCL and the majority of status report (out of three laboratory reports) related to Standard Quality (SQ)/ Not of Standard Quality (NSQ) shall be treated as final report".

OSMCL shall derecognise/ blacklist the defaulting supplier for that item for a period of three (03) years from the date of issue of letter to the concerned firm, "if two (02) or more batches of that item come out to be NSQ in the process mentioned above".

Following the above mentioned process, two (02) batches of subject item have been declared as NSQ by two out of three empanelled laboratories for each batch for not complying the Assay Test as per IP.

It is to mention here that M/s. Zee Laboratories Ltd., in whose favour the Purchase Order was issued, has accepted the tender conditions and supplied the drug. Therefore, after its drugs are being declared as NSQ, as per the procedure envisaged in N.I.T, the firm cannot turn around and challenge the test reports contrary to the agreed terms.

Since reports of empanelled laboratories shall be acceptable to both OSMCL and the supplier as per terms and conditions of the tender, the reply of the firm in response to Show Cause Notice is not sustainable in the eye of law and therefore liable to be rejected.

That, as per PO Clause No. 5(h)(ii) read with Bid Condition No. 6.39.8.1(ii) of Bid Reference No. OSMCL/2017-18/DRUGS-DHS/02, M/s. Zee Laboratories Ltd., Uchani G.T. Road, Karnal, Haryana - 132001 having manufacturing unit at Behind 47, Industrial Area, Paonta Sahib - 173025(HP) is hereby, derecognised/blacklisted for the item Paracetamol Paediatric Oral Suspension IP (125mg/5ml) for a period of three (03) successive 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 & the firm shall not be allowed to participate in the tender process of Odisha State Medical Corporation Ltd. for the said item during the above mentioned period.


Archana Patnaik, I.A.S.
Managing Director, OSMCL

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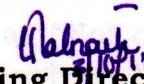
Memo No. 15283 /Dt. 03.10.2018.

Copy forwarded to M/s. Zee Laboratories Ltd., Uchani G.T. Road, Karnal, Haryana - 132001 for information.


**Managing Director,
OSMCL**

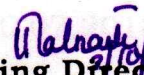
Memo No. 15284 /Dt. 03.10.2018

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


**Managing Director,
OSMCL**

Memo No. 15285 /Dt. 03.10.2018

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


**Managing Director,
OSMCL**

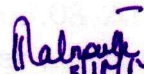
Memo No. 15286 /Dt. 03.10.2018

Copy forwarded to the GM - Operation (D & S)/GM (F & A), OSMC for information.


**Managing Director,
OSMCL**

Memo No. 15287 /Dt. 03.10.2018

Copy forwarded to Sr. Manager (IT), OSMC for information and necessary action.


**Managing Director,
OSMCL**