



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

Order No. :18424 /OSMCL/QA/1429/2018

Date : 22.11.2018

ORDER

M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road Bye Pass, Amritsar - 143001, Punjab was placed with orders to supply Inj. Ondansetron (2mg/ml) IP vide Purchase Order No. CR18152 Dtd.07.02.2018 & CR18304 Dtd.21.04.2018. 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 three approved NABL accredited laboratories empanelled by Odisha State Medical Corporation Ltd. (OSMCL), which was communicated to the supplier by enclosing the copies of test reports vide this office letter No. 12960 dtd.25.08.2018.

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.	Ref. PO No. & Date	Reason for declaring NSQ	Mfd. By
01	I-16163	02/2018	01/2020	CR18152 07.02.2018	Sample failed to comply w.r.t the Sterility test & Bacterial Endotoxin test	M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar - 143001, Punjab.
02	I-16183	02/2018	01/2020	CR18152 07.02.2018 CR18304 21.04.2018	Sample failed to comply w.r.t the Sterility test & Bacterial Endotoxin test	

In view of the above M/s. Jackson Laboratories Pvt. Ltd. was issued with Show Cause Notice (SCN) vide this office letter No. 13114 dtd.28.08.2018 seeking explanation within seven (07) days of receipt of the letter as to why it shall not be derecognised/blacklisted for the item Inj. Ondansetron (2mg/ml) IP 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 SCN dtd.28.08.2018, the notice-firm vide letter dtd.13.09.2018 alleged that they had asked for certain information at Sl. No. 1 to 4 of their letter No. 995 dtd.28.08.2018 in response to this office intimation letter No.12960 dtd.25.08.2018.

In the letter No.995 dtd.28.08.2018 of the supplier received through e-mail on 04.10.2018, the supplier alleged neither to have received letter bearing No.12960 dtd.25.08.2018 nor the copies of test reports sent by OSMCL. In response to that it is informed that this office letter No. 12960 dtd.25.08.2018 along with copies of test reports were sent through supplier's official/ authorised mail and the hard copies through speed post, which were delivered on 30.08.2018 as per the record of India Post.

(P.T.O)

In his letter dtd.28.08.2018, the supplier had requested to enlighten him on the following points.

1. Total number of ampoules received batch wise with its distribution chart.
2. Is there any complaint from any Hospital, Doctor or Paramedical Staff?
3. Has any patient complained about shivering, fever, nausea after injecting the impugned drug?

As regards to point No.1, being the supplier the information is available with him.

As regards to point No. 2 to 4, it is mentioned here that, as per Clause No. 5(a) of Purchase Order (PO) No. CR18152 "All the item(s) supplied at the warehouse shall be quarantined for quality testing by OSMCL and shall only be allowed for distribution after getting the Standard Quality (SQ) test reports from the approved NABL accredited laboratories empanelled by OSMCL". Also as per the said PO Clause No. 5(d) "In case of NSQ report of the sample from the empanelled NABL accredited laboratory, two other portions of the sample shall be sent to two different empanelled NABL accredited laboratories. In that case the majority of status report (out of three laboratory reports) related to NSQ/SQ shall be treated as final report". Since, the batches under question have been declared as NSQ in the above process at the quarantine stage before being released for public distribution, supply of information at Sl. No. 2 to 4 of the letter dtd.28.08.2018 of the supplier does not arise.

The supplier in his reply dtd.13.09.2018 to SCN has also raised "In case of non-compliance with the test of sterility, the practical test is more authentic because in any injectable failing in Sterility & Bacterial Endotoxin test, the patient gets severe adverse reaction like shivering, fever, nausea etc."

In response to that it is informed that the two batches of subject injection have been declared as NSQ by empanelled laboratories in the quarantine stage for not complying with Sterility & Bacterial Endotoxin test. Hence, it is highly illogical to subject the said batches for practical testing to observe any adverse reactions like shivering, fever, nausea etc.

The supplier in his reply has also raised "as per IP the test of sterility is to be repeated with same number of containers". The supplier has quoted the relevant extract from the monograph of IP.

"If the test is declared to be invalid, repeat with same number of units as in the original test. If no evidence of microbial growth is found in the repeat test, the preparation under examination complies with the test of sterility. If microbial growth is found in the repeat test and confirmed microscopically, the preparation under examination does not comply with the test for sterility".

In response to the above, it is stated that the laboratories have tested the two batches of subject item as per the monograph prescribed under IP, based on which the batches have been declared as NSQ.

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As requested vide letter dtd.13.09.2018, the supplier was allowed to appear for personal hearing before the Managing Director, OSMCL on dtd.15.10.2018, which was rescheduled on 29.10.2018 as per the supplier's request through letter dtd.13.10.2018.

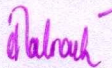
The authorised person of M/s. Jackson Laboratories Pvt. Ltd. appeared before the authorities of OSMCL on 29.10.2018 and submitted reply dtd.29.10.2018. In that reply, the supplier has expressed disagreement with reports issued by the laboratories empanelled by OSMCL and requested to get the samples retested at Appellate Laboratory i.e. Central Drugs Laboratory (CDL), Kolkata.

In response to that it is stated that the batches of subject drug have been tested and declared as NSQ by approved NABL accredited laboratories empanelled by OSMCL. There is no provision for retesting of items declared as NSQ by empanelled laboratories in the appellate laboratory as per the existing tender terms and conditions.

It is to mention here that M/s. Jackson Laboratories Pvt. Ltd. in whose favour the purchase order was issued has accepted the tender conditions and supplied the subject drug. Since reports of empanelled laboratories shall be acceptable to both OSMCL and the supplier as per terms and conditions of the tender, hence the reply of the firm vide letter dtd.28.08.2018, 13.09.2018 & 29.10.2018 are not sustainable in the eye of law and therefore liable to be rejected.

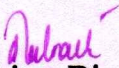
Therefore, as per PO Clause No. 5(h)(ii) read with Bid Condition No. 6.39.8.1(ii) of Bid Reference No. OSMCL/2017-18/DRUGS-DHS/02, M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road Bye Pass, Amritsar - 143001, (Punjab) is hereby, derecognised/blacklisted for the item Inj. Ondansetron (2mg/ml) IP 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.


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

Memo No. 18425 /Dt. 22.11.2018

Copy forwarded to M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar - 143001, Punjab for information.


Managing Director,
OSMCL

(P.T.O)

Memo No. 18426 /Dt. 22.11.2018

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

Dabouli
**Managing Director,
OSMCL**

Memo No. 18427 /Dt. 22.11.2018

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

Dabouli
**Managing Director,
OSMCL**

Memo No. 18428 /Dt. 22.11.2018

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

Dabouli
**Managing Director,
OSMCL**

Memo No. 18429 /Dt. 22.11.2018

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

Dabouli
**Managing Director,
OSMCL**