Uttar Pradesh Medical Supplies Corporation Limited

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Ref. No.: UPMSC/ MD/QC/2019/13967 Date: 18 October, 2019

OFFICE ORDER

The Firm Himalaya Meditek Private Limited Plot No, 35 & 36, Pharma city, Selaqui Industrial Area, Dehradun-248197(HP) was declared L-1 in tender No.-UPMSCL/Drugs-002/26 dated 29/05/2018 for 17 drugs including drug code no. D01006 Lignocine HCl with Adrenaline Inj. (Lignocaine HCl 20mg/ml Adrenaline Bitartate Eq. to Adrenaline 5mcg/ml) in 30 ml vial & vide this office letter No. (1288/UPMSCL/Drugs/LOI/2018 dated 15/10/2018), the Letter of Intent (LOI) was issued to the firm.

The Firm Himalaya Meditek Private Limited had supplied batches no. HLI126C (DM-03/2019, DE-02/2021), HLI875F (DM-06/2019, DE-05/2021) & HLI877F (DM-06/2019, DE-05/2021) against PO no. UP/UP/HQ/18/45/1(10281862338) dated 03/11/2018 of drug Lignocine HCl with Adrenaline Inj. 30ml vial to different heath facilities of Uttar Pradesh.

After the perusal and examination of the tender documents and other relevant documents it is evident that the process of sampling for Quality Control as per Tender conditions, drugs samples were collected of all three batches by authorized pharmacist Quality Control of the Corporation and sent to one of the empanelled NABL Certified Laboratory of the Corporation namely M/s Sophisticated Industrial Materials Analytical Lab Pvt Ltd., A-3/7 Mayapuri Industrial Area, Phase –II, New Delhi-110064.

The result received by UPMSCL from the above laboratory on 26.08.2019 indicated the drug to be "Not of Standard Quality" as per the Drugs and Cosmetics Act, 1940 and their Rules, 1945 [as per Indian Pharmacopoea] with respect to pH.

According to the condition of Tender Document/ Agreement, again the two samples of above said drug batch were sent to two different empanelled NABL certified laboratories namely M/s Interstellar Testing Centre Pvt Ltd and M/s Manisha Analytical Laboratory Pvt Ltd on 28.08.2019 for re-analysis.

According to analysis report dated 23.09.2019 from M/s Intersteller Testing Centre Pvt Ltd for all three batches the samples were found "NOT OF STANDARD QUALITY" as per in the Drugs and Cosmetics Act 1940 and their Rules, 1945 [as per Indian Pharmacopeia] with respect to pH.

Again according to analysis report dated 28.09.2019 from M/s Manisha Analytical Laboratory Pvt. Ltd for all three batches of samples were found "NOT OF STANDARD QUALITY" as per the Drugs and Cosmetics Act 1940 and their Rules, 1945 [as per Indian Pharmacopeia] with respect to pH.

Notice regarding supply of "Not of Standard Quality" for batch no. HLI126C (DM-03/2019, DE-02/2021), HLI875F (DM-06/2019, DE-05/20121) & HLI877F (DM-06/2019, DE-05/2021) was sent to Firm Himalaya Meditek Private Limited on 03/10/2019 (Ref. No. UPMSCL/QC/2019/13640) and response letter was given by firm (Ref. No. HIMALAYA/UPMSCL/L-2 Dated 07/10/2019) which was received to UPMSCL on 10.10.2019 by e-mail.. In response the firm has stated that –

1. Drugs stored in a prescribed storage condition were tested by govt. approved accredited laboratory M/s Shree Krishna Analytical Services and Shree Sai Test House Pvt Ltd and it complies with all the quality standards including assay of Lignocine and Adrenaline.
2. Drugs were supplied to Corporation after proper testing at their end and were found to be of standard quality.
3. Samples were not collected as per prescribed Forms and Provisions of Section 23 of Drugs and Cosmetics Act 1940.
4. The firm has alleged that the proposed action of Corporation is unfair and unreasonable and violation of Firm's rights enshrined in Article 21 of the Constitution of India and will violate equity, fair play and natural justice.

5. Firm submitted that in instant case there is no legally admissible evidence like Form 13 or Form 2 as appended to the Drugs and Cosmetics Rules 1940 are not on record and thus the drugs in question cannot be said to be "Not of Standard Quality". Thus any action of "Stopping Sales of Subject Drugs" is neither justified nor sustainable in law rather will violate all canons of equity, fair play and natural justice.
6. The Firm has expressed its dis-satisfaction on the report of the Corporation's empanelled Laboratories which are approved/ certified by NABL.
7. Placing reliance upon Section 23 of the Drugs and Cosmetics Rules 1940, the firm has alleged violation of the statutory provisions while collecting the samples and procuring the report from the Corporation's empanelled Laboratories. The Firm has also raised doubts with regard to the Testing, Protocol and Method adopted by the empanelled Laboratories of the Corporation which are certified/ approved by NABL. Accordingly, the Firm has raised a challenge to the Reports of the empanelled Laboratories.

There was a clear and specific prescription in the Tender Notice as well as in the Agreement that after the delivery of the drugs by the concerned Firm, in order to ascertain that the drugs supplied are of Standard Quality, the samples would be collected and shall be sent to any of the NABL accredited Laboratories which have been empanelled by the Corporation. In case the Test Report indicates that the drug is "Not of Standard Quality", another portion of retained sample shall be sent to another two empanelled Laboratories for confirmation of results and if the sample is again declared to be "Not of Standard Quality" by any of the two NABL accredited and Corporation's empanelled Laboratories, the drug supplied shall be concluded to be "Not of Standard Quality". In case if there is only one or two empanelled Laboratories for conducting the Test on a specified drug, then in that case the confirmatory Test shall be done at Government Analyists Laboratory. In the instant case, there are more than two NABL accredited Laboratories which are empanelled by the Corporation and the Reports of all the three empanelled Laboratories indicate the drug supplied by the Firm as "Not of Standard Quality" and therefore, the request for re-analysis of the samples from Government Testing Laboratories is unsustainable.

Merely because a Quality Certificate was submitted by the Firm, the same would not mitigate or nullify the reports of the empanelled Laboratories of the Corporation which are NABL accredited as all the three reports of the empanelled Laboratories have reported the drugs to be "Not of Standard Quality".

The Firm's reliance on Section 23 of the Drugs and Cosmetics Act 1940 also appears to be misplaced as Section 23 of the Act lays down a procedure to be adopted by an Inspector appointed for taking any sample of the Drug. The said Inspector refers to the Inspector appointed by the Central Government or State Government under Section 21 of the Drugs and Cosmetics Act 1940. In the instant case the drug samples have been collected in terms of the Tender conditions and therefore, Section 23 of the Drugs and Cosmetics Act 1940 are not-applicable.

All the Bidders including the Firm in question is well versed with the Terms and Conditions of Tender Document which provides that the drug samples shall be sent to the NABL accredited Laboratory empanelled by UPMSCL and if the drug is reported to be "Not of Standard Quality", the retained sample shall be sent to other two NABL accredited Laboratories empanelled by UPMSCL. In case any one out of two empanelled Laboratory report the drug to be "Not of Standard Quality", then it shall be concluded that the drug is "Not of Standard Quality". It is worth mentioning here that all the three NABL accredited Laboratories empanelled by UPMSCL have reported the drug to be "Not of Standard Quality".

In above case final report is "Not Of Standard Quality" on the basis of three analytical laboratory test report. Thus firm Himalaya Meditek Private Limited has violated the *Tender clause No.13.(i) "If two batches of any drug supplied by the supplier is found not of standard quality, then the supplier shall be blacklisted for that particular drug for a period of 3 (three) year."* And *violated Agreement clause no-4(a), "If two batches of any drug supplied by the supplier is found not of standard quality, then the*

supplier shall be blacklisted for that particular drug for a period of 3 (three) year.", by supplying not of standard quality (NSQ) three batches (HLI126C,HLI875F& HLI877F)of the drug Lignocine HCl with Adrenaline Inj IP 30ml vial to different health facilities of Uttar Pradesh .Hence, the drug Lignocine HCl with Adrenaline Inj (Lignocaine HCl 20mg/ml Adrenaline Bitartate Eq. to Adrenaline 5mcg/ml)in 30ml vial of the firm M/s Himalaya Meditek Private Limited is,hereby ,blacklisted for three years from the date of issue of this order.

Managing Director
UPMSCL

C.C. to:-

1. Principal Secretary, Medical Health & Family Welfare, UP;
2. Secretary, Medical Health & Family Welfare, UP;
3. Mission Director, National Health Mission (NHM);
4. Director General, Medical & health Services, Swasthya Bhawan, UP;
5. Director General, family Welfare, UP;
6. Himalaya Meditek Private Limited Plot No 35 & 36, pharma City, Selaqui Industrial Area, Dehradun- 248197 (Himachal Pradesh)

Managing Director
UPMSCL