

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT:

THE HONOURABLE MR.JUSTICE P.R.RAMACHANDRA MENON

FRIDAY, THE 10TH DAY OF APRIL 2015/20TH CHAITHRA, 1937

WP(C).No. 10155 of 2015 (T)

PETITIONER(S) :

**M/S.UNICURE (INDIA) LIMITED,
AN ISO 9000-2008 CERTIFIED COMPANY, C-22 & 23,
SECTOR-3, NOIDA - 201 301, UTTAR PRADESH,
REPRESENTED BY ITS MANAGING DIRECTOR ABDUL MATEEN.**

**BY SRI.P.RAVINDRAN (SENIOR ADVOCATE)
ADV. SRI.SREEDHAR RAVINDRAN**

RESPONDENT(S) :

- 1. KERALA MEDICAL SERVICES CORPORATION LIMITED,
THYCAUD P.O., THIRUVANANTHAPURAM - 695 014,
REPRESENTED BY MANAGING DIRECTOR.**
- 2. THE MANAGING DIRECTOR,
KERALA MEDICAL SERVICES CORPORATION LIMITED,
THYCAUD P.O., THIRUVANANTHAPURAM - 695 014.**
- 3. STATE OF KERALA,
REPRESENTED BY ITS SECRETARY,
HEALTH AND FAMILY WELFARE DEPARTMENT,
THIRUVANANTHAPURAM - 695 001.**

**R1 & R2 BY ADV. SRI.M.AJAY, S.C
R3 BY SR.GOVERNMENT PLEADER SRI.K.C.VINCENT**

**THIS WRIT PETITION (CIVIL) HAVING COME UP FOR ADMISSION
ON 10-04-2015, THE COURT ON THE SAME DAY DELIVERED THE
FOLLOWING:**

Msd.

APPENDIX

PETITIONER(S)' EXHIBITS

EXHIBIT P1: TRUE COPY OF THE CERTIFICATE DATED 06.06.2014.

EXHIBIT P2: TRUE COPY OF THE LICENCE VALID TILL 31.12.2016.

**EXHIBIT P3: TRUE COPY OF THE CERTIFICATE OF REGISTRATION ISSUED BY
THE INDIAN STANDARD ORGANIZATION.**

**EXHIBIT P4: TRUE COPY OF THE NON CONVICTION CERTIFICATE
DATED 18.12.2014.**

**EXHIBIT P5: TRUE COPY OF THE RELEVANT EXTRACT OF THE TENDER
NOTIFICATION DATED 08.01.2015
NO:KMSCL/DRGED/I&II/RC/2015/001.**

**EXHIBIT P6: PHOTOSTAT COPY OF THE NOTICE DOWNLOADED BY
THE PETITIONER FROM THE WEBSITE DATED 25.03.2015.**

RESPONDENT(S)' EXHIBITS

**EXHIBIT R1(A): A TRUE COPY OF THE INSPECTION REPORT OF
THE MANUFACTURING FACILITIES OF THE PETITIONER
COMPANY DATED 02.03.2015.**

//TRUE COPY//

P.A.TO JUDGE.

Msd.

P.R. RAMACHANDRA MENON, J.

W.P.(C) No.10155 of 2015

Dated this the 10th day of April, 2015

JUDGMENT

Rejection of the technical bid submitted by the petitioner in furtherance to Ext.P5 tender notice in respect of '**Tablets**', while qualifying the petitioner in respect of the other items, made the petitioner to approach this Court by filing this writ petition.

2. The specific case of the petitioner is that, the petitioner satisfies all the requirements in terms of the tender notice and at no point of time, was the petitioner informed as to any defect with regard to the credentials. It is stated that, the course being pursued and proceeded by the 1st respondent to oust the petitioner from the field of '**Tablets**' is per se wrong and illegal in all respects and hence the challenge.

3. The averments and allegations have been sought to be rebutted by the 1st respondent by filing a Counter Affidavit, also producing copies of the relevant materials. It is pointed out that, the rejection is made on the basis of the report of the inspecting team, as to the infrastructure available in the establishment of

the petitioner. The fact that the tender quoted by the petitioner in respect of 'other items' stands already accepted, itself is a pointer to the fact that there is no instance of malafides and that a proper merit rating has been done.

4. Heard Sri. P. Ravindran, the learned Senior Counsel appearing for the petitioner as well as Mr. M.Ajay, the learned Standing Counsel appearing for the respondents.

5. During the course of hearing, it is brought to the notice of this Court by the learned Senior Counsel for the petitioner that, there is absolutely no basis for the insinuation made against the petitioner and that there could not have been any such circumstance as well, since the infrastructure has to be provided and maintained strictly in conformity with the statutory requirements, particularly the terms as prescribed under 'Schedule M' of the Drugs and Cosmetics Rules, 1945. Various provisions in this regard are referred to and brought to the notice of this Court. The learned Senior Counsel for the petitioner also pointed out that, by virtue of the mandate under the relevant provisions of law, that, if at all any defect is there with regard to the 'GMP', it is open for the petitioner to have it rectified. There is

a stipulation to the effect that, in the course of inspection, if any defect is noted, the same has to be published in the Website. No such publication has been effected in the Website and no material has been produced before this Court to substantiate the satisfaction of the requirement.

6. Ext.R1(a) is the report, wherein the different divisions/heads are dealt with separately. In respect of '**Tablet** division', various traits were required to be analysed and appreciated by the inspection team. As many as 1 to 27 instances/columns are provided under the head 'Oral Solid Dosage Forms (Tablets and Capsules)'. All the queries have been answered in the '**positive**' and there is no entry, which stands against the petitioner. Based on the said entries/fact finding exercise, the following remarks have been endorsed by the authority, who conducted inspection:

"The tablets, capsules and powders offered for sale to Kerala Medical Services Corporation are manufactured in a very congested area. The ORS powder manufacturing area and capsule manufacturing units are dedicated units with automation. Proper environmental control is also maintained in those areas. The tablet section is found to be highly congested and many molecules are manufactured in adjacent rooms without any environmental control. So the manufacturing area is to be closely monitored to prevent possible cross contamination and mix up."

However, coming to the end portion of the report, the recommendation by the concerned Inspector is in the following terms:

"The firm had offered 98 products for supply to KMSCL. The products offered to manufacture as capsules, external applications, sex hormones, oral liquid preparation, Beta lactum products may be accepted. The tableting section is found to be highly congested and there is no proper environmental monitoring. There is chance for cross contamination and mix up of different tablets due to improper monitoring of the environment. The walls, floors and corners of rooms are accumulated with dust and dirt, cleaning steps also not satisfactory. The firm is found to be extended to the 30 year old initial building without any uniflow and logical arrangements. The tablets can be accepted only after rectification of the defects detected.

The party had not permitted to take photographs inside the firm."

7. After considering the materials on record, this Court finds that there are glaring inconsistencies between the remarks given at page 52 (of the Counter Affidavit) and the remarks in the concluding portion by way of recommendation. It appears that, the insinuating circumstance as it forms part of the recommendation in respect of **Tablet** division is actually not in existence when compared with the remarks made with reference to the traits 1 to 27 at page 52 (of the Counter Affidavit). In

other words, there is no dissatisfaction, incompetence or such other adverse circumstances with regard to the '**Tablets**', though there are some minor/adverse observations with regard to the infrastructure in respect of the other items like oral liquid preparations, the sterile products and such other items. It appears that the facts got mixed up. This Court finds considerable force in the submission made by the learned Senior Counsel for the petitioner that the rejection of tender submitted by the petitioner in respect of the '**Tablets**' is not correct or sustainable and is liable to be intercepted.

8. The learned counsel appearing for the 1st respondent submits that, the said respondent was pursuing the matter on a transparent basis and that the decision taken was on the basis of the report of the external inspection team. It is also stated that, by virtue of the enabling provisions under the statute and in terms of the tender, the said respondent has the power and competence to conduct inspection/re-inspection at any point of time. It is also pointed out that, the 1st respondent is ready and willing to conduct a further inspection in the premises of the petitioner and to have the matter considered accordingly, subject

to satisfaction of a cost of Rupees 'One lakh' by the petitioner towards incidental expenses.

9. The learned Senior Counsel for the petitioner submits that, the petitioner is ready to satisfy the said requirement.

10. In the said circumstances, there will be a direction to the petitioner to deposit a sum of Rupees 'One lakh' before the 1st respondent forthwith, upon which, a further inspection shall be conducted in the premises of the petitioner as to the availability of the infrastructure and the GMP. It is open for the 1st respondent to open the tender and to proceed with further steps, simultaneously conducting an inspection at the premises of the petitioner with notice as aforesaid. Finalisation of the tender in respect of the '**Tablets**' shall be subject to the outcome of the inspection and verification as mentioned above.

The writ petition is disposed of.

**P.R. RAMACHANDRA MENON,
JUDGE**

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