IN THE HIGH COURT OF JUDICATURE AT MADRAS

Orders Reserved on : 25..09..2019
Orders Pronounced on : 21..10..2019
CORAM

THE HON'BLE MR.JUSTICE V.BHARATHIDASAN

Writ Petition No.33857 of 2017
and
W.M.P.No.37542 of 2017

M/s.Syndicate Pharma
Rep. by its Authorized Signatory,
No.188, Sector-F, Sanwar Road,
Indore, Madhya Pradesh 452 015.

... Petitioner

-Versus-

1.The Secretary to Government,
Health and Family Welfare,
Government of Tamil Nadu,
Fort St. George, Chennai 600 009.

2.The Managing Director,
Tamil Nadu Medical Services Corporation Limited,
No.417, Pantheon Road, II Floor,
Egmore, Chennai 600 008.

3.The Drugs Inspector,
Alandur Range I/c,
O/o The Assistant Director of Drugs Control,
Kancheepuram Zone, Chennai 600 006.

4.Andhra Pradesh Medical Services
and Infrastructure Development Corporation,
2nd Floor, Plot No.9, Survey No.49, IT Park,
Mangalagiri, Guntur,
Rep. by its Managing Director.

5.Chhattisgarh Medical Services Corporation Limited,
3rd Floor, Goving Sarang Vyavasayik Parisar,
New Rajendra Nagar,
Raipur, Chattisgarh,
Rep. by its Managing Director.

[Respondents 4 and 5 were impleaded as per order dated 09.01.2018 made in W.M.P.S.No.604 and 605 of 2018]

... Respondents

Writ Petition filed under Article 226 of the Constitution of India, praying to issue a Writ of Certiorarified calling for the records of the 2nd respondent under file Ref.No.DIC076/TNMSC/QC2016-17 dated 08.12.2017 passed in consequence of Tender Ref.No.001/M(P)/DRUG/TNMSC/2015 dated 23.01.2015 and to quash the order dated 08.12.2017 in Ref.No.DIC076/TNMSC/QC2016-17 dated 08.12.2017and also for a consequential direction to the respondents to permit the petitioner to participate in future tenders with costs.

For Petitioner : Mr.T.D.Selvan Babu

For Respondent(s) : Mr.I.Sathish, Addl. Government Pleader for R1 and R3

Mr.Shivakumar for R2

ORDER

This writ petition has been filed challenging the order passed by the 1st respondent black listing the drug - Oral Rehydration Salt (ORS) IP manufactured and supplied by the petitioner company for a period of two years from 08.12.2017 to 07.12.2019 and forfeiting the security deposit of Rs.1,57,073/-.

2. According to the petitioner, they are pioneer in the manufacturing of the drug - Oral Rehydration Salt (ORS) IP for the last several years and they maintain the state of the art manufacturing facility at its premises at Indore in Madhya Pradesh. The petitioner company is more vigilant and cautious in maintaining the quality of the drug as they primarily cater to the Government supplies. The petitioner company owes its success due to high quality drugs at affordable price. They supplied more than 1000 batches of ORS IP to the respondents over a period of 8 years continuously. In the year 2015, the 2nd respondent floated a tender for supply of ORS IP. As per the tender conditions, the respondent would make payments against supply only after their Empaneled Laboratory has declared the drug as 'standard quality'. The 2nd respondent used to send the sample to their empaneled laboratories at various places in India by taking random sample of drugs supplied by its suppliers and obtain a report before making payment to the tenderers for the supplies made. The 2nd respondent had also made payment for the supplies made after following the above procedure which would go to show that the ORS IP supplied to the 2nd respondent was a drug of standard quality.

3. While so, on 06.03.2017, the 2nd respondent sent a letter to the petitioner stating that when samples drawn on 20.10.2016 by the Drugs Inspector, Alandur Range in Kancheepuram District were sent for analysis by the Government Analyst, the drug was found to be 'not of standard quality'. In the said circumstances, the 2nd respondent had given a warning to the petitioner company that if any further batch of same drug declared as 'not of standard quality' action would be initiated as per the terms of the tender conditions. Thereafter, a show cause notice dated 17.03.2017 was issued to the petitioner by the 2nd respondent calling upon the petitioner as to why the product should not be blacklisted for two years as per clause 20.2.1 (e) (iii) of the tender document 2015-16 as the sample test failed in quality test for Assay content of less than 50% as per the Government Analyst Report. Thereafter, the petitioner obtained a copy of the Government Analyst's report from the 2nd respondent and on 25.04.2017, the petitioner sent a detailed reply to the 2nd respondent stating that after the warning issued to the petitioner that action would be initiated if two more samples are declared as not of standard quality and as no such situation had arisen thereafter, the subject was closed with the warning. Therefore, it is not open to the 2nd respondent to reopen the issue and issue a show cause notice. As per clause 20.2.1(e), the 2nd respondent ought to have drawn one more sample for analysis before issuing the show cause notice. The petitioner had already challenged the report of the Government Analyst as incorrect by letter dated 20.02.2017 addressed to the Drugs Inspector, Alandur Range and requested him to send the 3rd portion of the sample to the appellate laboratory namely, Central Drugs Laboratory, Kolkata as per the statutory procedure and thus, the report of the Government Analyst is not conclusive as per Section 25(3) of the Drugs and Cosmetics Act, 1940.

4. It is further stated by the petitioner that the report of the Government Analyst suffered from calculation error and the analyst adopted a wrong procedure and if correct procedures and calculation were applied, the content of dextrose would be not less than 99% of the label claim. The petitioner appeared in person before the 2nd respondent on 09.06.2017 and made a detailed submissions followed by further written submissions by letter dated 13.06.2017. The petitioner was able to demonstrate that there was no violation of tender conditions and the show cause notice has been issued based on the wrong calculation. The show cause notice has been issued without following the procedure contemplated under Clause 20.2.1 (e) of the Tender condition. According to the petitioner, without sending the sample from the same batch for test by the Central Laboratory and without considering none of the objections raised by the

petitioner, the impugned order has been passed which is totally illegal. The impugned order is, therefore, liable to be set aside.

5. The 2nd respondent filed counter affidavit contending that the tender was invited for supply of ORS IP for 2015-16. The samples are tested by the empaneled laboratory of this respondent as a precondition for payment is matters of record. In the instant case, the statutory sample drawn by the Drugs Inspector had failed in the Government Drugs Testing Laboratory and report was to the effect that the drug was "not of standard quality". Further, the drug must be stable during its shelf-life, whereas the concerned drug was failed within its expiry date. Initially, the drug was of standard quality as it passed in the empaneled laboratories, but, later on, it had been declared as 'not of standard quality' by the Government Analyst from the Drug Testing Laboratory. The test was carried on by the Government Analyst as per the standards of pharmacopoeia for patent or proprietary medicines, prescribed for the purpose of the Second Schedule to the Act. In the above circumstances, under section 25 (3) of the Drugs and Cosmetics Act, 1940 and Clause 20.2.1 (g) of Tender 2015-16, the Government Analyst's report is final and conclusive.

6. The 3rd respondent - Drugs Inspector, Alandur Range, Kancheepuram Zone, filed his counter affidavit contending that on 20.10.2016, the sample of ORS IP manufactured by the petitioner was drawn for analysis from Urban Primary Health Center, Gandhi Street, Pammal, Chennai by the then Drugs Inspector, Alandur Range (I/c), Kancheepuram Zone and the same was sent for drug testing laboratory for test. The test report proved that the drug was not of standard quality as the sample does not conform to IP specification for oral rehydration salts with respect to the contend of Dextrose (Anhydrous). Thereafter on 20.01.2017, a letter was sent to the Medical Officer, Urban Primary Health Centre, Gandhi Street, Pammal, Chennai 600075, to disclose the name and address of the person from whom the said drug was acquired as per Section 18-A of the Drugs and Cosmetics Act, 1940 and the Rules thereunder. Accordingly, the Medical Officer by his reply dated 20.01.2017 informed that the drugs were acquire from TNMSC Limited, Drugs Ware House, K.K.Nagar, Chennai under OGR No.N020323 dated 16.10.2015. Then, on the same day, a letter was issued to the Drug Ware House In charge, Drug Ware House, TNMSC Limited, Drugs Ware House, K.K.Nagar, Chennai by the then Drugs Inspector, Alandur Range to disclose the name and address of the person from whom the said drugs were acquired as per Section 18-A of The Drugs and Cosmetic Act, 1940 and the rules thereunder. Accordingly, a reply dated 23.01.2017 was received from the Drug Ware House, K.K.Nagar, wherein it was disclosed that the drugs were acquired from the petitioner company. Thereafter, on 25.01.2017, a show cause memo was

issued to the petitioner for the contravention of Section 18 (a) (i) of The Drugs and Cosmetics Act, 1940 and Rules, 1945 and for having manufactured and distributed for sale of the subject not of standard quality drugs and requested to furnish the subject drug under Section 18-B of the said Act and third sealed portion of the sample drawn for test or analysis was also sent separately by the then Drugs Inspector, Alandur Range (i/c), Kancheepuram Zone.

7. Thereafter, on 09.02.2017, a show memo reminder - I was issued to the petitioner for which the petitioner issued a reply stating that they have analyzed the control sample and found to comply in all aspects with specification as per IP including the test for assay of Dextrose (Anhydrous). The petitioner further challenged the report of the Government Analyst, Drugs Testing Laboratory, Chennai and requested to send the samples to Central Drugs Laboratory (CDL) Kolkatta. As the samples sent by the petitioner on 20.02.2017 along with the reply were received only by 27.02.2017, the samples could not be sent to Central Drugs Laboratory for test as the life of the drug was then going to expire by the end of February, 2017.

8. It is also stated by the 3rd respondent that ORS is widely prescribed in case of dehydration in the gastric complications to replace the salt and nutrient for compensating electrolyte imbalance to save the life of the patients. If the said drug as such is issued by the public it would not serve the purpose and the conditions may be worsen and may become critical. Since it is Government supply, the drug is mainly consumed by the poor and needy patient and if the drugs which are not of standard quality are administered to the patient, the same would pose serious threat to the health of the poor and needy patient and also cause grievous hurt to the user.

9. The learned counsel appearing for the petitioner would contend that the impugned order blacklisting the petitioner company for two years from 08.12.2017 to 07.12.2019 for supplying Oral Rehydration Salt (ORS) and forfeiting the security deposit of Rs.1,57,073/- has been passed without following the mandatory requirements under Section 25(4) of the Drugs and Cosmetics Act, 1940 and without forwarding the sample to the Central Drugs Laboratory, Kolkatta, for test. The impugned order has been passed only based on the report of the Government Analyst in violation of mandatory requirement. That apart, the respondents 1 and 2 had not only failed to follow the procedure contemplated under clause 20.2.1 of the Tender Condition but failed to consider the objections raised by the petitioner.

10. Per contra, the learned counsel appearing for the 2nd respondent would contend that the Government Analyst report

would clearly show that the drugs supplied by the petitioner are of sub standard quality. The petitioner company also did not make a request in time to send the sample to the Central Drugs Testing Laboratory at Kolkatta for test and they had deliberately kept quiet and let the life of the sample drugs get expired and deliberately dispatched the samples along with reply at the fag end to see that by the time when the sample reaches the Central Drugs Laboratory, its shelf life would get expired. Therefore, now, it is not open to the petitioner to contend that the mandatory provisions have not been followed by the respondents 1 and 2. The impugned orders has been passed after following the terms and conditions of the tender and also due procedures prescribed under the Act and Rules and no illegality or irregularity can be attached to the same.

11. The learned counsel would further contend that the petitioner company was blacklisted for two years from 08.12.2017 to 07.12.2019 for supplying Oral Rehydration Salt (ORS) besides forfeiture of security deposit and the period of blacklisting is going to expire on 07.12.2019. There is no violation of mandatory procedures as contended by the petitioner company and the writ petition is liable to be dismissed.

12. I have considered the rival submissions carefully.

13. The primordial contention of the learned counsel for the petitioner is that before blacklisting the petitioner company, the 2nd respondent did not follow the procedures contemplated in the tender conditions in respect of blacklisting of a supplier and the respondents 1 and 2 have failed to follow even the mandatory requirements under Section 25 of The Drugs and Cosmetics Act, 1940 and the rules thereunder.

14. Before going into the facts of the case it would be useful to refer to the Tender conditions in respect of blacklisting for quality failure.

15. Clause 20.2.1 of the Tender conditions provides for black listing for quality failure which reads as follows:-

> "20.2.1. Quality Test by the Empanelled Laboratories of TNMSC
>
> (a) Each and every batch of drugs / medicines supplied by the supplier shall be subjected to quality test by the Empanelled laboratories.
>
> ... ...
> ... ...
>
> (e) If the sample fails in quality test and report is received certifying that sample is "NOT OF STANDARD QUALITY", one more sample shall

be drawn from the same batch and to be sent to Government Laboratory for quality testing.

... ...

... ...

(iii) If such Sample fails in quality test for ASSAY content of less than 50% as per the Government Analyst report,such product of the tenderer will be blacklisted for two years.

(iv) However, TNMSC reserves the right to reject the drugs based on reports from empanelled laboratories with the applicable penal provisions.

16. Clause 20.2.2 of the Tender conditions speaks of quality test by Statutory Authorities and Clause 20.2.4 prescribes procedure for black listing.

(i) Clause 20.2.2 of the Tender conditions for supply of drugs and medicines reads as follows:-

(a) On complaint from Drug Inspector(s) during their Test of statutory sample, that the particular drug has been reported to be of "NOT OF STANDARD QUALITY", the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals will be retrieved. If the sample is reported to have less than 50% of content, the particular product will be blacklisted for 2 years from the date of intimation of blacklisting.

(b) If 3 batches of a particular item supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and/or other parameters, then the particular item of the firm shall be blacklisted for a period of 2 years from the date of intimation after observing the procedure laid down in Para 20.2.4.

(c) If a single batch of any product(s) supplied by the company / firm declared as Adulterated / spurious / misbranded by the Government Authorities during the shelf life of the product supplied irrespective of tender period, the company/firm shall be blacklisted for a period of 5 years from the date of intimation after observing procedure laid down in Para 20.2.4.

(ii) Clause 20.2.4 of the Tender conditions for supply of drugs and medicines reads as follows:-

Clause 20.2.4 Procedure for Blacklisting

(i) On receipt of report from Govt. Analyst / Drug Testing Laboratory indicating that a particular Item/Drug is "NOT OF STANDARD QUALITY / ADULTERATED / SPURIOUS / MISBRANDED (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the Managing Director, TNMSC may take appropriate action on merits of the case and impose penalty including the blacklisting of the particular item of the product / company or firm as deemed fit besides forfeiture of Security deposit.

(ii) If a particular item of the drug has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for that particular item floated by the TNMSC until the period of blacklisting is over.

(iii) If a supplier company/firm is blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the TNMSC until the period of blacklisting is over."

17. As per clause 20.2.1 of the Tender conditions, each and every batch of drugs supplied by the petitioner would be subjected to quality test by the empanelled laboratories and a random check would be conducted from the samples collected from the ware house, only after quality test, the drugs would be supplied to various hospitals. If the quality test fails one more samples will be drawn from the batch and the same will be sent to the Government Drug Testing Laboratory for test as per Clause 20.2.1 (e). If the sample passes the quality test by the Government Laboratory, the drugs would be issued to the hospital and if the sample fails the quality test, action would be initiated as per the tender conditions and the drugs would be sent back to the supplier.

18. As per clause 20.2.1 (g), in all the cases the reports received from the Government Drug Testing Laboratory / decision of TNMSC Limited will be conclusive and final and binding on the suppliers. Clause 20.2.4 of the Tender conditions prescribes the procedures for

blacklisting.

19. In the instant case, admittedly, the sample which was sent for the analysis to the Government Laboratory failed the quality test and the report of the Government Analyst would clearly go to show that sample drawn and sent for test fails in fails in quality test for ASSAY content of less than 50% and

therefore, the drug was declared to be not of standard quality. Based on the report of the Government Analyst only, the 2nd respondent had issued a show cause notice to the petitioner as per clause 20.2.4 of the Tender conditions. Thereafter, on receipt of the reply and after hearing the petitioner, the 2nd respondent not being satisfied with the explanation submitted by the petitioner passed the impugned order black listing the drug - Oral Rehydration Salt (ORS) IP manufactured by the petitioner company for two years.

20. On a careful perusal of the entire materials available on record, this court is of the considered view that the 2nd respondent had scrupulously followed the mandatory procedures contemplated in the Tender Conditions before passing the impugned order.

21. Now, it is contended by the petitioner that the 2nd respondent did not follow the procedure contemplated under Section 25 of The Drugs and Cosmetics Act, 1940 and without sending the sample for final analysis by the Central Drug Testing Laboratory, the 2nd respondent ought not to have blacklisted the petitioner based on the Government Analyst's report only. This contention cannot be countenanced for the simple reason that the shelf life of the drug was to expire on 28.02.2017. Though the show cause notice was issued to the petitioner on 09.02.2017 by the 2nd respondent along with the report of the Government Analyst's report, knowing fully well that the shelf life of the drug was going to be expired then, the petitioner had kept quiet and sent a reply dated 20.02.2017 which was received by the 3rd respondent only on 27.02.2017 just one day before the expiration of the shelf life of the sample drug. In the above circumstances, the 3rd respondent was not in a position to send the sample for testing by the Central Drug Testing Laboratory. The petitioner having kept quiet without requesting for further test by the Central Drug Testing Laboratory in time and neglected to avail the opportunity, now, it is not open to them to contend that the drug was not forwarded to the Central Drug Testing Laboratory at Kolkatta. Had the petitioner company acted swiftly in forwarding the sample for third test by the Central Drug Testing Laboratory, the 3rd respondent would have forwarded the same for test immediately.

22. Considering the entire materials available on record this court is of the view that there is no illegality or procedural irregularity in the order passed by the 2nd respondent black listing the petitioner company. Thus the writ petition is devoid of merits and the same deserves only to be dismissed.

In the result, the Writ Petition is dismissed. No costs. Consequently, connected WMP is closed.

Sd/-
Assistant Registrar(CS VI)

//True Copy//

Sub Assistant Registrar

kmk

To

1.The Secretary to Government,
Health and Family Welfare,
Government of Tamil Nadu, Fort St. George, Chennai 600 009.

2.The Managing Director, Tamil Nadu Medical Services Corporation Limited, No.417, Pantheon Road, II Floor, Egmore, Chennai-8.

3.The Drugs Inspector, Alandur Range, O/o The Assistant Director of Drugs Control, Kancheepuram Zone, Chennai 600 006.

+1cc to Mr.T.D.Selvan , Advocate SR.No. 88379
+1cc to Mr.R.Shiva kumar , Advocate SR.No. 87991
+1 cc to Government Pleader Sr.No. 88686

Writ Petition No.33857 of 2017

A.SK(29/11/2019)