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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 28.01.2022

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THE HONOURABLE MR.JUSTICE KRISHNAN RAMASAMY

W.P.No.7088 of 2017
and W.M.P.Nos.7700 & 7701 of 2017

M/s.Centurion Laboratories,
G/5, Industrial Estate,
AT & Post Gowra,
Vadodara-390 016.

... Petitioner

Vs.

1. The Secretary to Government,
Health & 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.

... Respondents

PRAYER : Petition filed Under Article 226 of the Constitution of India praying to issue a Writ of Certiorarified Mandamus, to call for the records of the respondent No.2 under File RefNo.DICO90/WH-05/TNMSC/QC/2015-16, quash the order dated 22.02.2017 passed in consequence of Tender Ref.No.004/M(P)/VETDRUG/TNMSC/2013, dated 03.04.2013 and consequently, direct the respondents to permit the petitioner to participate in future tenders and continue to place orders under the Schedule mentioned Tenders for its remaining/extended period with costs.

For Petitioner : Mr.AR.L.Sundaresan, SC for
Mr.T.D.Selvan Babu

For R1 : Mr.M.Shahjahan, Spl.G.P.

For R2 : M/s.Shivakumar & Suresh

ORDER

This Writ Petition has been filed to issue a Writ of Certiorarified Mandamus, to call for the records of the



respondent No.2 under File RefNo.DICO90/WH-05/TNMSC/QC/2015-16, quash the order dated 22.02.2017 passed in consequence of Tender Ref.No.004/M(P)/VETDRUG/TNMSC/2013, dated 03.04.2013 and consequently, direct the respondents to permit the petitioner to participate in future tenders and continue to place orders under the Schedule mentioned Tenders for its remaining/extended period with costs.

2. The case of the Petitioner in brief, is as follows:

2.1 The Petitioner, M/s.Centurion Laboratories is a leading manufacturer of a wide Allopathic, Ayurvedic and Veterinary drugs for the last more than 20 years. The petitioner has maintained state of art manufacturing and testing facility and advanced research laboratory at its premises at Vadodara, Gujarat, employing more than 500 employees. The Petitioner has been a successful tenderer and supplier of its allopathic and veterinary drugs to the Respondents for the last more than 15 years in a row, without any complaints as regards supply or quality. The Petitioner was awarded with contract for the supply of veterinary drug named "Oxytetracycline Hydrochloride Solution 5% w/v for the year 2013-2014, pursuant to the tender notification issued by the Respondent no.2 vide Tender Ref.No.004/M(P)/VETDRUG /TNMSC/2013).

2.2 As per Clause 11.8 read with Clause 16.4 of the Tender conditions, the respondent will make payments against supply only if the samples of the drugs are declared as "Standard Quality". The respondent no.2 compulsorily sends the samples to the Empanelled Laboratories at various places in India by taking random sample of drugs and obtains a report before making the payment to the Tenderers for the supplies made by them. The Petitioner supplied the Veterinary Drug named "Oxytetracycline Solution" 5% w/v and received the payments as per conditions of the Tender and the said supply of drugs was received and kept in the warehouse of the Respondent no.2. Subsequent orders were also placed to the the petitioner and pursuant to the same, stocks were also distributed to various Veterinary Hospitals, without any complaints and the stocks also got exhausted and thereby the tender is fulfilled by the petitioner.

2.3 While so, after the supply was completed, the Petitioner received a letter dated 25.06.2015 from Respondent no. 2 stating that the sample of the drug had been drawn by the Drug Inspector and on being sent to Govt. Analyst, it was declared as not of 'Standard quality' by a report dated 20.10.2014 and asked the petitioner to take the stock back from the warehouse. According to the petitioner, the shelf time of the drug has been expired when the Petitioner received the letter dated 25.06.2015. However, when the Petitioner approached the warehouse, the



petitioner was informed that the stocks have already been exhausted even before 25.06.2015 and also learnt that there was no complaint received from any of the Veterinary Hospitals to which the drug was supplied.

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2.4 Subsequently, the respondent No.2 issued a show cause notice dated 06.06.2016 to the petitioner after a lapse of one year. The petitioner gave a detailed reply dated 16.06.2016. However, the respondent No.2, after receipt of the detailed reply dated 16.06.2016, dissatisfying with the explanation given by the petitioner, issued proceedings dated 22.02.2017, impugned in the Writ Petition, holding that the subject drug Oxytetracycline Solution 5% w/v supplied by the petitioner failed in Quality checking done by the Government Laboratory and has been reported as "Not of standard Quality/Spurious/Misbranded". As such, by invoking Clause 19.3 of Tender-2013-14 and Section 17-B(d) of Drugs and Cosmetics Act, 1940, the respondent No.2 has ordered blacklisting the petitioner firm for a period of 5 years for the supply of "Not of standard Quality/Spurious/Misbranded" drug, Oxytetracycline Solution 5% w/v (D.Code: D46) to Tamil Nadu Medical Services Corporation Limited and also ordered forfeiture of Security Deposit of Rs.3,07,505/- which was deposited by the petitioner. Challenging the impugned order, dated 22.02.2017, the petitioner has come forward with the present Writ Petition.

3. A counter affidavit has been filed on behalf of the 2nd respondent, wherein, it is stated as under:

3.1 The 2nd respondent, Tamil Nadu Medical Services Corporation Limited (in short, TNMSC') is a Nodal Agency for procurement and distribution of drugs, etc., for about 11,000 Government medical institutions all over Tamilnadu. The respondent has been following the provisions of the Tenders Act as well as two cover system viz., Cover A and Cover B viz., Technical bid and price bid respectively. Clause 20 of the terms and conditions of the Tender deals with blacklisting for quality failure. Clause 20.2.2(c) empowers the respondent to blacklist the Company/firm for a period of five years, if a single batch of product 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.

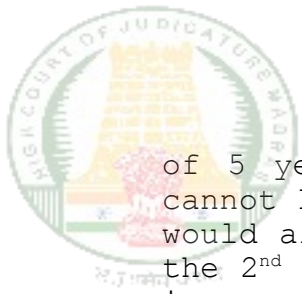
3.2 The present tender relates to the supply of veterinary drug Oxytetracycline Hydrochloride Solution 5% w/v for the year 2013.14. It is a matter of record that statutory sample drawn by the Drugs Inspector had failed in the Government Drugs Testing Laboratory. The drug must be stable during its shelf-life, whereas, the concerned drug supplied by the petitioner,



failed to meet the standards within its expiry date. Initially, the drug is of the standard quality as it passed in the empanelled laboratories, but later, it has been declared as "Not of standard Quality" by the Government Analyst. Since the drug do not conform to General description and identification, the Drugs Inspector has directed the failed drug as "spurious" as per clause 17(B) (d) of the Drugs and Cosmetics Act, 1940.

3.3 It is further stated that Clause 20.2.2(c) of Tender clearly provides that even if a single batch of the product supplied by the petitioner is declared as spurious by the Government Authorities during the relevant tender period, the company/firm shall be blacklisted for a period of 5 years from the date of blacklisting after observing procedure laid down in para 20.2.4. According to the 2nd respondent, the petitioner has not impleaded the Drugs Inspector nor challenged the Report of the Drugs Inspector, who categorically held that the drug supplied by the petitioner was spurious. Therefore, after observing the procedure laid down in the paragraph No.20.2.4, which deals with the procedure for blacklisting, a show cause notice dated 06.06.2016 was issued and an explanation was called for from the petitioner. The petitioner responded and gave explanation vide letter dated 14.09.2015, which was found not satisfactory and not valid by the 2nd respondent. Accordingly, by invoking Clause 19.3 of Tender-2013-14 and Section 17-B (d) of Drugs and Cosmetics Act, 1940, the 2nd respondent has rightly ordered blacklisting of the petitioner firm for a period of 5 years for the supply of "Not of standard Quality/Spurious/Misbranded" drug, Oxytetracycline Solution 5% w/v (D.Code: D46) to Tamil Nadu Medical Services Corporation Limited and also ordered forfeiture of Security Deposit of Rs.3,07,505/- of the petitioner, which requires no interference. With these averments, the 2nd respondent has sought for dismissal of the Writ Petition.

4. The learned counsel appearing for the petitioner would contend mainly contend that the Report of the Government Analyst has reported that the drug is not of standard quality and does not state that the drug to be spurious and therefore, blacklisting the petitioner for 5 years does not arise and it was not provided as such under tender terms. He would further contend that 2nd respondent has not considered the statements made by the Government Analyst who tested the sample report and opined that the drug is not of standard quality, while, the Drugs Inspector who relied upon the report of the Government Analyst, opined that the drug is spurious, however, the 2nd respondent by relying upon both the statements which are contradictory to each other, without going into the merits of the case as per the tender conditions, imposed prohibition by ordering blacklisting the product of the petitioner for a period



of 5 years and also forfeiture of the security deposit, which cannot be sustained and the same is liable to be set aside. He would also submit that the petitioner is a preferred supplier of the 2nd respondent for the past 15 years and there was no quality issue arose in the past, while so, the 2nd respondent apart from banning the petitioner for 5 years for the subject drug, also suspended orders in respect of subsequent tenders also.

5. On the other hand, the learned counsel appearing for the 2nd respondent would submit that the Government Analyst report would clearly show that the drug supplied by the petitioner is not of standard quality and the petitioner also did not make any request with regard to re-testing of samples under Section 25(4) of the Drugs and Cosmetics Act, 1940. As per Section 25(3) of the Act, the petitioner has to notify in writing to the Drugs Inspector within 28 days from the date of receipt of the letter, which the petitioner did not so. Therefore, he would contend that once the petitioner failed to make request for re-test the product, the petitioner cannot question the report of the Drug Inspector, that too after a substantial lapse of time. The petitioner has also not made the Drug Inspector as a party nor challenged his report.

6. The learned counsel for the 2nd respondent would also contend that under Section 17-B of the Drugs and Cosmetics Act, 1940, if a drug is held to be spurious and is not standard quality, no manufacturer is allowed to manufacture or sell the same. As per Section 25(3) of the Act and Clause 20.2.1(g) of Tender conditions, the Government Analyst Report is final and conclusive. Therefore, based upon the Report of the Government Analyst, by invoking Clause 19.3 of Tender-2013-14 and Section 17-B(d) of Drugs and Cosmetics Act, 1940, the 2nd respondent has rightly ordered blacklisting of the petitioner firm for a period of 5 years for the supply of "Not of standard Quality/Spurious/Misbranded" drug and also ordered forfeiture of the security deposit, which requires no interference by this Court. In support of his contentions, the learned counsel for the 2nd respondent relied upon a decision of this Court reported in "2019 SCC OnLine Mad 24658 (Syndicate Pharma, rep. by its Authorized Signatory versus Secretary to Government and others)".

7. This Court has given its anxious consideration to the rival submissions made by the learned counsel for the parties and perused the entire materials available on record.

8. Before dealing with the matter, it is appropriate to extract the relevant Clauses contained in the Tender-2013-14:

"19. Deduction & other penalties on account of quality failure:



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19.1 & 19.2

19.3 For the supply of Adulterated/Spurious/Misbranded drugs to TNMS, the firm/company shall be blacklisted by TNMSC and no further supplies shall be accepted from the firm/company. The Tenderer shall also not be eligible to participate in tenders of Tenders Inviting Authority of TNMSC for supply of Veterinary Drugs for a period of 5 years from the date of blacklisting. In respect of supply of NOT OF STANDARD QUALITY drug(s) to TNMSC, the produce shall be blacklisted by TNMC and no further supplies shall be accepted for the particular drug(s). The Tenderer shall also not be eligible to participate in terms of TNMSC Ltd., for supply of such Veterinary Drugs for a period of 2 years from the date of blacklisting. In addition, the Director of Drugs Control of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

"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.

(b) & (c)

(d) Such quality passed batches if received after declaration of result of the earlier supply, the same will be again subjected to testing and the latest report of that particular batch will be binding on the entire quantity of the batch supplied and recovery will be made for the entire quantity of that batch irrespective of purchase order date or date of supply etc."

(e)

(f) If 3 batches of a particular drug 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 drug of the firm shall be blacklisted after observing procedure laid down in Para 20.2.4 besides forfeiture of Security Deposit of that particular product(s).

(g) In all the cases the reports received from the Government Drug Testing Laboratory/decision of TNMSC Ltd will be



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conclusive and final and binding on the suppliers.

"20.2.2. Quality Test by Statutory Authorities:

(a) On complaint from Drug Inspector(s) during their Test of field 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 topped. 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 initiation of blacklisting.

(b) If 4 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 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 produce 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.

"20.2.4. PROCEDURE FOR BLACKLISTING:

(i) On receipt of report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Drug/Drug is NOT OF STANDARD QUALITY / ADULTERATED / SPURIOUS / MIS-BRANDED (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 drug of the product/company or firm as deemed fit besides forfeiture of security deposit."

9. A perusal of the above Tender Clauses, it is clear that as per Clause 20.2.1, each and every batch of drugs / medicines supplied by the supplier shall be subjected to quality test by the Empanelled laboratories and a random check would be conducted from the samples collected from the warehouse, 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 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. As per Clause 20.2.1 (g) in all 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 procedure for blacklisting.

10. In the present case, it is not in dispute that the drug supplied by the petitioner, viz., Oxytetracycline Solution 5% w/v, was found as 'not of standard quality' as could be seen from the Report of the Government Analyst. The Government Analyst sent the Report of analysis with the remarks, stating that "the sample does not conform to Oxytetracycline Hydrochloride Solution with respect to General Description and Identification". Consequently, the petitioner was issued with show cause notice dated 23.07.2015, calling for explanation as per Clause 20.2.4 (i) of the tender condition. But the petitioner sent reply letter after lapse of nearly 11 months on 21.06.2016, disputing the report of the Government Analyst, stating that the drug supplied by the petitioner was not properly stored and the bottle contains the drug, bears the words in bold letters as "shake well before use", which was not followed by the Government Analyst and as such, the Government Analyst report is not a conclusive. According to the petitioner, Government Analyst reported citing sediments, the officer did not shake well the bottle before analysing the sample resulting in the oxytetracycline deposited at the bottom of the bottle not mixing with the solvent and not answering the test of identification. It is also the case of the petitioner is that before resorting to ordering blacklisting of the petitioner, the 2nd respondent has not provided an opportunity of personal hearing to the petitioner.

11. However, according to the 2nd respondent, the Government



Analyst has analyzed the subject sample as per the standards of USP and hence, the claim of the petitioner is not substantial since as per Clause 20.2.1(g) of Tender conditions, the reports received from the Government Drug Testing Laboratory will be conclusive and final and binding on the suppliers.

12. It is pertinent to note that the Government Analyst has given report declaring that the drug supplied by the petitioner was tested and found 'not of standard quality'. Therefore, as per the Clause 20.2.2(a) extracted above, if the sample is reported to be of "not of standard quality", the particular product will be blacklisted for 2 years from the date of intimation of blacklisting. But as per Clause 20.2.2 (c) only when the drug supplied by the company/firm declared as Adulterated/spurious/misbranded by the Government Authorities during the relevant tender period, the company/firm shall be blacklisted for a period of 5 years from the date of blacklisting after observing procedure laid down in para 20.2.4.

13. While so, as could be seen from the impugned order, dated 22.02.2017, it has been mentioned that the petitioner firm has failed in quality checking done by the Government Laboratory and has been reported as of "not of standard quality/spurious/misbranded and it is not specific, as regards whether the subject drug was 'not of standard quality or spurious or misbranded'. However, while invoking Section 17-B (d) of Drugs and Cosmetics Act, 1940, the 2nd respondent termed the drug supplied by the petitioner as "spurious drug" and thereby, invoking Clause 19.3 of Tender conditions and Section 17-B(d) of the Act, the 2nd respondent ordered blacklisting of the petitioner firm for a period of 5 years, which, in the opinion of this Court, cannot be sustained inasmuch as even in Clause 19.3 of tender conditions (extracted above), which was relied on by the 2nd respondent, it has been clearly mentioned that in respect of supply of NOT OF STANDARD QUALITY drug(s) to TNMSC Ltd., the product shall be blacklisted by TNMSC and no further supplies shall be accepted for the particular drug(s). The tenderer shall also not eligible to participate in tenders of TNMSC Ltd. for supply of such Veterinary Drugs for a period of 2 years from the date of blacklisting.

14. At this juncture, it is worthwhile to refer the Sections 16 & 17 of the Drugs and Cosmetics Act, 1940, which read as under:

16. Standards of quality. – For the purposes of this Chapter, the expression "standard quality" means—
- (a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and
 - (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.



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(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

17. Misbranded drugs.—For the purposes of this Chapter, a drug shall be deemed to be misbranded—

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

17-A. Adulterated drugs.— For the purposes of this Chapter, a drug shall be deemed to be adulterated,—

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

17-B. Spurious drugs.—For the purposes of this Chapter, a drug shall be deemed to be spurious,—

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of



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an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product."

15. A perusal of the above, it is clear that standard quality of a drug means, it complies with the standard set out in the second schedule, viz., standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being, in force and such other standards as may be prescribed. As per Sections, 17, 17-A & B three types of drugs have been classified, viz., Misbranded drugs, Adulterated drugs and Spurious drugs and each one has been described with clear specifications (stated supra) as to how such drugs, viz., Misbranded, Adulterated and Spurious can be termed. Of course, these three kinds of drugs, viz., Misbranded, Adulterated and Spurious will come within the purview of 'not of standard quality' category, but it does not mean that all substandard drugs are misbranded, adulterated or spurious since each substandard drug has been described with clear specifications.

16. In the present case, the Government Analyst specifically reported that the drug supplied by the petitioner, is 'not of standard quality', while so, in the impugned order, the 2nd respondent considered the drug supplied by the petitioner as 'spurious' under category (d) of Section 17-B, which described that the drug deemed to be spurious if it has been substituted wholly or in part by another drug or substance and invoked Section 17-B (d) of the Act. But it is pertinent to note that nowhere in the impugned order it has been mentioned that the drug supplied by the petitioner has been substituted wholly or in part by another drug and the name of such drug was not mentioned.

17. Moreover, the Government Analyst also mentioned the drug only as 'not of standard quality' since the ingredients of either spurious or misbranded or adulterated drug were not identified in respect of the subject drug supplied by the petitioner otherwise, he would have specifically given report stating that it is a spurious or misbranded or adulterated. Therefore, since the subject drug cannot be termed or fallen under any of the above three categories, the impugned order of the 2nd respondent treating it as spurious, cannot be sustained. Thus, this Court is unable to come to a conclusion that the drug supplied by the petitioner was a spurious drug. In such circumstances, since the Government Analyst reported that the subject drug is 'not of standard quality' this Court is of the



made by the petitioner till the disposal of the Writ Petition. Now, this Court removed the blacklisting of the petitioner firm for a period of 5 years, but confirmed only in respect of the subject product for a period of 2 years alone, which period also is over by this time. Hence, it is made clear that the petitioner can be permitted to participate in future tenders and place the orders. No costs. Consequently, connected WMP is closed.

Sd/-
Assistant Registrar(CCC)

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Sub Assistant Registrar

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To

1. The Secretary to Government,
Health & 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.

+lcc to the Government Pleader, S.R.No.6000

W.P.No.7088 of 2017

RK(CO)
CT 16/02/2022