IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 29.01.2020

Pronounced on :28.02.2020

CORAM

THE HONOURABLE MR. JUSTICE C.V.KARTHIKEYAN

W.P.No.25770 of 2019
and
W.M.P.No.25218 of 2019

M/s. Jackson Laboratories Private Limited,
A Private Limited Company Registered under
The provisions of the Companies Act, 1956
Represented by its Managing Director
Mr.Jugal Kishore
22-24, Majitha Road, Bye Pass, P.O.Khanna Nagar
Amritsar - 143 004. ... Petitioner

..Vs..

1.Secretary to Government
Health and Family Welfare (H2) Department,
Secretariat,
Chennai - 600 009.

2.The Chairman
Tamil Nadu Medical Services Corporation Ltd
Board-Cum-Principal Secretary,
Department of Health and Family Welfare,
Government of Tamil Nadu,
Chennai - 600 008.

3.Tamil Nadu Medical Services Corporation Ltd.,
(A Government of Tamil Nadu undertaking)
Represented by its Managing Director,
No.147, Pantheon Road, 2nd Floor,
Egmore, Chennai - 600 008.

4.General Manager (Drugs)
Tamil Nadu Medical Services Corporation Ltd,
No.147, Pantheon Road, 2nd Floor,
Egmore, Chennai - 600 008.

... Respondents

PRAYER : Petition filed under Article 226 of the Constitution of India praying to issue a Writ of Certiorari, calling for the records on the file of the 1st respondent in issuing Letter No.46953/H2/2017-6 dated 26.06.2019, and quash the same.

For Petitioner :Mr.P.R.Raman, Senior Counsel
for P.Ramesh Kumar

For R1 :Mr.R.Govindasamy,
Additional Government Pleader

For RR2 to 4 :Mr.Shivakumar

ORDER

This Writ Petition has been filed by M/s. Jackson Laboratories Private Limited, Amritsar, Punjab, in the nature of Writ of Certiorari, calling for the records on the file of the 1st respondent, namely, the Secretary to Government, Health and Family Welfare (H2) Department, Chennai, with respect to letter No.46953/H2/2017-6 dated 26.06.2019 and quash the same.

2. In the affidavit filed in support of the writ petition, it had been stated by the Managing Director of the Petitioner company, that the petitioner is a licensed Pharmaceutical manufacturing unit based in Amritsar, Punjab, and engaged in the business of manufacturing pharmaceuticals drugs. It had been claimed that the petitioner has been awarded ISO 9001:2008 Certification for excellence in Total Quality Management. The petitioner has also been awarded the Quality Vendor Certification by the Diretor General Quality Assurance, New Delhi. It has been claimed that the petitioner has installed the latest technology machinery for production and packaging of pharmaceutical drugs. The petitioner also claimed that they have been provided with Good Laboratory Practices Certificate.

3. It had been further stated that the petitioner participated in the Tender No.002/M(P) DRUG/TNMSC/2017 dated 16.06.2017 floated by 4th respondent namely, the General Manager (Drugs), Tamil Nadu Medical Services Corporation Ltd., (TNMSC) Chennai, for supply of various medicines. The bid submitted by the petitioner was accepted with respect to a number of products, where they were the lowest bidder. The 4th respondent directed the petitioner to submit an agreement to supply various items at the quoted rates. An agreement was also submitted by the petitioner on 22.11.2017. It was stated that the petitioner was awarded one product (Tab. Carbimazole 5 mg)

with specifications as 'Coated Tablets' in packing of blister strips.

4. The petitioner addressed the 3rd and 4th respondents namely, the Managing Director of Tamil Nadu Medical Services Corporation Ltd., and the General Manager (Drugs) of Tamil Nadu Medical Services Corporation Ltd., that this tablet is usually supplied as loose Uncoated Tablets in a bottle pack. But the petitioner was still asked to supply the said tablets as Coated Tablets in blister packs. The petitioner then supplied a large quantity of this product throughout Tamil Nadu. In accordance with the statutory resolutions, the drug was tested by the 3rd and 4th respondents. It was found to be of Standard Quality. It was claimed that after sometime a different Drug Inspector tested the samples from different hospitals. One such sample was tested by Dr.S.Gopinath, Drugs Inspector, CDSCO, South Zone, Chennai, from the premises of the warehouse K.K.Nagar. On testing, the Government Analyst declared 'Nil' content. It was claimed that the Drugs Inspector also visited the factory and made detailed enquiry. It was claimed that the drug is light sensitive and thermolible drug and is required to be stored below 30^0C whereas the temperature in Chennai crosses 45^0C. It was stated that the date of sampling was on 23.05.2017, the date of receipt in Laboratory was on 26.05.2017, the date of Testing was between 12.07.2017 and 20.07.2017 and the date of report was 11.08.2017.

5. The petitioner claimed that the defects had come due to improper storage. It was stated that on the basis of the report, the 3rd respondent took cognizance without sending the report to the petitioner. The petitioner received a show cause notice dated 15.07.2017 from the 4th respondent stating that the Tablet Carbimazole Batch No.12701 had been reported to be 'Not of Standard Quality' and explanation was sought why the product should not be blacklisted for two years. The petitioner claimed that by letter dated 18.08.2017, they had given the explanations in response to the show cause notice. The petitioner also sought personal hearing.

6. The petitioner received another show cause notice dated 28.09.2017 along with the report in Form 13 dated 11.08.2017 from the Drugs Inspector, CDSCO, South Zone, Chennai. The petitioner again submitted their submissions on 12.10.2017. They requested that the sample be retested under Section 25(4) of the Drugs and Cosmetics Act, 1940 by the Director CDL, Kolkata, the Appellate Authority under the Act. The petitioner claimed that the 4th respondent relied on the report filed by the Government Analyst, CDL under Form 13. It was further claimed that the 4th respondent even without considering the submissions made by the

petitioner passed the impugned order dated 07.12.2017, blacklisting the petitioner company for a period of five years from 05.08.2017 and forfeiting the security deposit of Rs.16,88,530/- and by another order dated 12.12.2017 also blacklisted the petitioner company for a period of 5 years from 05.12.2017 and also forfeited the Security Deposit of Rs.16,88,530/-. It is claimed that the 4th respondent had passed the orders dated 07.12.2017 and 12.12.2017, blacklisting the petitioner for 5 years and forfeiting the Security Deposit, in gross violation of Principles of Natural Justice. It had been further stated that the petitioner had filed an appeal on 16.12.2017 which is pending before the 1st respondent. It was claimed that since no orders were passed, the petitioner had filed W.P.No.3123 of 2018 seeking a direction against the 1st respondent to pass orders in the Appeal. The petitioner thereafter filed two writ petitions in W.P.Nos.34182 and 34186 of 2018, to call for the records of the 3rd respondent with respect to orders dated 07.12.2017 and 12.12.2017 and quash the same. An order was passed on 21.12.2018 directing the 1st respondent to dispose of the appeal dated 16.12.2017 on merits, after affording an opportunity of hearing. It was stated that finally on 12.02.2019, the petitioner received a letter dated 08.02.2019 calling upon the petitioner to appear for personal hearing on 12.02.2019. It is claimed that the letter was received by the petitioner at 03.00 p.m on 12.02.2019. The time fixed for hearing was at 11.00 a.m. Thereafter, on representation made by the petitioner, the hearing was refixed to 02.04.2019. The petitioner claims that they appeared on 02.04.2019 and gave oral and written submissions. However, it is claimed that the 1st respondent had rejected the appeal by an order dated 26.06.2019. The petitioner claimed that the said order had been passed without application of mind. It is under these circumstances, that the petitioner had filed the present Writ Petition.

7. A counter affidavit had been filed on behalf of the 1st respondent, in which it had been stated by the Joint Secretary to Government, Health and Family Welfare Department, Chennai, that the 3rd respondent namely, Tamil Nadu Medical Services Corporation Ltd., had issued a tender for supply of Carbimazole Tablets IP 5mg (D.Code:270) and the petitioner had participated in the tender for supply of the same during the period 2016-17. The said drugs are used as Anti Thyroid drugs. A drug is said to be spurious, if on consumption, it is totally ineffective and does not give any relief to the patients. It is stated that normally the said tablets have a shelf life of two years. The tablets supplied by the petitioner were tested and it was found that the 1st, 2nd and 3rd samples failed the quality test and the 4th sample was found to be spurious. The 4th sample was again tested and it was again found to be not of standard quality. It

was stated that under clause 20.2.4(i) of the Tender, if the drug is not of Standard Quality / Adulterated / Spurious / Mis-branded, then a show cause notice must be issued and on receipt of the explanation, an appropriate decision has to be taken and a penalty can be imposed including blacklisting the particular drug of the product / company besides forfeiture of Security Deposit. It is claimed that the petitioner signed the Purchase Order. A show cause notice was issued by the 3rd respondent. The petitioner had replied on 12.02.2017. The drugs were supplied only after proper testing. It was specifically claimed that the 4th respondent did not agree to retest the samples under Section 25(4) of the Drugs and Cosmetics Act, 1940. The petitioner was also afforded an opportunity to adduce evidence. However, the petitioner stated that since their Managing Director was a Senior person he could not come to Chennai. It was stated that when a special procedure was laid down under the Drugs and Cosmetics Act, 1940, the said procedure has to be followed. The petitioner had failed to file a statutory appeal before the Appellate Authority. It was stated that therefore the report of the Drugs Inspector cannot now be questioned. It was however stated that according to the provisions of the Drugs and Cosmetics Act, 1940 and also the terms of the Tender, the decision of the Government Analyst is final. It was stated that however, the same drugs were also retested with the Government Analyst. It was found that the contents were Nil. It was stated that the 3rd respondent had followed the procedure as per the Clause 20.2.4(i) of the tender condition. It was stated that the drugs failed the test. It was stated that the drugs were meant for consumption of patients and the respondents had a responsibility to ensure that only quality drugs are supplied to the patients. It was stated that the impugned order was passed after considering all aspects. It was reiterated that the drugs supplied by the petitioner were substandard. It was stated that the drugs were tested in the Government Laboratory and later again tested in the Central Drugs Laboratory (Appellate Laboratory) Kolkatta, wherein, it was found that it was a spurious drug. It was for that reason, that the Government blacklisted the petitioner company for a period of 5 years. It was stated that even if one drug was found to be spurious, then the Company has to be blacklisted. It was stated that the respondents had applied the terms of the Tender and also the provisions of the Drugs and Cosmetics Act, 1940. It was stated that the Writ Petition has no merits and should be dismissed.

8. A counter affidavit had been filed on behalf of the 4th respondent, in which, it had been stated that a Tender had been issued for supply of Carbimazole Tablets IP 5 mg (Drug Code:270). The petitioner had participated in the tender. The averments in the counter affidavit of the 1st respondent were repeated. It was also stated that the tablets supplied by the

petitioner failed in the drug test and the 3rd batch was found to be spurious and therefore, it was again tested and it was found 'not of standard quality'. It was also stated that under Clause 20.2.2(c) of the Tender condition, if a single batch of any product is found to be spurious then the Company should be blacklisted for a period of 5 years. It was again reiterated that the correct procedure had been followed and that the Writ Petition has to be dismissed.

9. Heard arguments advanced by Mr.P.R.Raman, learned Senior Counsel for P.Ramesh Kumar, learned counsel for the petitioner, Mr.R.Govindasamy, learned Special Government Pleader for the 1st respondent and Mr.V.Shivakumar learned counsel for the 2nd to 4th respondents.

10. I have also carefully considered the material records.

11. The petitioner M/s.Jackson Laboratories Private Limited, Amritsar, Punjab, is a Pharmaceutical Manufacturing Unit. They had participated in Tender.No.002/M(P) DRUG/TNMSC/2017 dated 16.06.2017 floated by the 4th respondent namely, the General Manager (Drugs), Tamil Nadu Medical Services Corporation Ltd., (TNMSC). The petitioner's bid was accepted. The tender was floated for supply of Carbimazole Tablets IP 5 mg (Drug Code:270). This was for supply of the tablets for the year 2016-2017. It must be kept in mind that TNMSC Limited, is a Nodal Agency for procurement and distribution of drugs, medical equipments, surgical and suture items etc., for about 11,000 Government Medical Institutions all over Tamil Nadu. It was stated that the tenders for procurement of drugs, medicines, surgicals and sutures are floated periodically. The specifications are finalized by a team of Specialists.

12. In the tender document, it had been specifically provided as follows:

> "BLACKLISTING FOR QUALITY FAILURE:
>
> 20.2.1. Quality Test by the Empanelled Laboratories of TNMSC:
>
> (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 conclusive and final and binding on the suppliers.

20.2.2.Quality Test by Statutory Authorities:

(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), as 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."

13. The petitioner supplied a huge quantity of tablets. The Drugs and Cosmetics, Act 1940, was in fact promulgated to regulate import, manufacture, sale and distribution of drugs and cosmetics. Chapter IV of the Act, relates to manufacture, sale and distribution of drugs and cosmetics.

14. Section 17 of the Drugs and Cosmetics Act, 1940 relates to Misbranded drugs. Section 17 is as follows:

"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 that 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."

15. Section 17(A) relates to Adulterated drugs. Section 17 (A) is as follows:

"17A. Adulterated drugs. -- For the purpose of this Chapter, a cosmetic 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 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 the purpose 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."

16. Section 17(B) relates to Spurious drugs. Section 17(B) is as follows:

"17B.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 intimation of, or is a

substitute for, another drug or resembles another drug in a manner likely to deceive or bear 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 identity with such other drug ; or

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

17. Section 18 provides for Prohibition of manufacture and sale of certain drugs and cosmetics. Section 18 (a)(i) is as follows:

"18. Prohibition of manufacture and sale of certain drugs and cosmetics. —From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf ,no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution or sell, or stock or exhibit or offer for sale —

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

.....

....."

18. Section 20 of the Act, relates to Government Analysts. Section 20 is as follows:

20. Government Analysts. — (1) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for

such areas in the state and in respect of such drugs or classes of drug or such cosmetics or classes of cosmetics as may specified in the notification.

(2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or subsection (2) of this section.

19. Section 21 of the Act, relates to Inspectors and Section 22 of the Act relates to the Powers of Inspectors.

20. Section 23 of the Act, relates to the Procedure to be followed by the Inspectors.

21. Section 25 of the Act, relates to Reports of Government Analysts. Section 25(3) of the Act, is as follows:

"Sec.25(3). Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report."

22. It is seen that a report signed by the Government Analysts shall be evidence of the facts stated and such evidence shall be conclusive unless the person within 28 days of the receipt of the copy of the report states in writing that he intends to adduce evidence to controvert the statements to the report.

23. Section 25(4) of the Act, is as follows:

> "Sec.25(4).(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein."

24. The said provision provides that where a person has stated his intention of adducing evidence, the Court may, cause the sample of the drug to be produced before the Magistrate and sent for test or analysis to the laboratories. It must be resulted that Section 25(4) of the Act can be resorted only when the person mentioned notifies in writing within 28 days that he proposes to adduce evidence in controversion to the report provided under Section 25(3) of the Act.

25. In the instant case, the Government Analyst, Drug Testing Laboratory, Chennai, on 01.06.2017 had given the following result of the analysis of the Carbimazole Tablets IP 5 mg (Drug Code:270) supplied by the petitioner.

ANALYSIS DONE	RESULT OF ANALYSIS	LABEL CLAIM/I.P.Specification
Nature of packing and quantity of the sample received.	Received 10 Blister strips containing 10 tablets each and kept in an original carton.	1x10x10 Tablets
Description	Orange colour coated tablet	Film coated tablet
Identification	Does not answer the identification test for carbimazole	
Disintegration	Conforms to IP specification.	
Assay Estimation of Carbimazole	Each tablet of average weight is found to contain NIL	Each tablet purports to contain 5 mg (IP Limit : 90% to 110% of Label claim).

26. The 3rd respondent had then issued a show cause notice on 02.08.2017 to the petitioner. In the same, the results of the Test of the Government Analyst had been given as follows:

SL. No	Batch No.	Po.No. & Date	Complaints & Random Samples	Govt. Analyst Remarks
1	T-13503	AI1912, dt:24/01/2017 AI2443 dt: 14/02/2017	Quality Failure	"The sample is not of standard quality as it does not conform to IP specification for Carbimazole tablets with respect to the content of Carbimazole."
2	T-13303	AI1912 dt: 24/01/2017 AI2443 dt: 14/02/2017	Quality Failure	

SL. No	Batch No.	Po.No. & Date	Complaints & Random Samples	Govt. Analyst Remarks
3	T-12112	AI1128 dt:04/11/2016	Quality Failure	"The sample is not of standard quality as it does not conform to IP specification for Carbimazole tablets with respect to the content of Carbimazole" (22.4% Assay content less than 50%)
4	T-12701	AI1128 dt: 04/11/2016 AI1912 dt: 24/01/2017	Survey sample by Drugs Inspectors, CDSCO, South Zone, Chennai - 06.	In the opinion of the undersigned the sample is of SPURIOUS QUALITY as defined in the Drugs and Cosmetics Act, 1940 and rules there under. The sample does not conform to the IP specification with respect to identification. Note: The tablets are labeled as film coated on the carton box whereas in strip they are labeled as uncoated.
			Based on CDSCO report, the sample is tested again.	The sample is not of standard quality as it does not conform to IP specification for Carbimazole tablets (Nil Content)

27. The 3rd respondent then quoted Clause 19(1) of the Tender condition and stated that under clause 20.2.1.(e).(iii) and 20.2.1(f) of the tender condition, if the samples fails in quality test, then the drug will be blacklisted for a period of two years. By the show cause notice, the petitioner was called to give an explanation within 7 days as to why action should not be taken to blacklist the product supplied by the petitioner. A second show cause notice was issued on 28.09.2017, since the sample was also deemed to be spurious drug. In the show cause notice, the petitioner was called upon to give an explanation

within 28 days, failing which necessary action will be taken against the petitioner. The report of the Central Drug Laboratory, Government of India, Kolkatta was also annexed along with the show cause notice under Form-13. The said report is as follows:

"FORM NO.13
CDL-8
See Rule 46

Certificate of Test or Analysis by Government Analyst under Section 25(1) of the Drugs Act, 1940.

.....
.....
.....

7.Result of test or analysis with protocols of tests applied.

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in drug Act, 1940 and rules thereunder for reasons given below:

Date of testing: 12.07.2017 to 20.07.2017.

Method : I.P.

Description	Orange film coated tablets supplied in blister strip pack. The tablets lack sufficient hardness		
Identification	Does not gives positive test for Carbimazole		
Assay	Found/tab	Claim/tab	Limit
Carbimazole	NIL	5 mg	90% to 110% of claim.
Remarks	Reason for declaring the sample as not of standard quality The sample does not conform to I.P with respect to Identification and Assay of Carbimazole and for the reason stated under Description. The sample is deemed to be spurious under Section 17B of Drugs & Cosmetics Act, 1940.		

No.32-10/2017-SS/DCA(S)-25/2485
Dated: 11.08.2017

(Arindam Basu)

Government Analyst
Central Drugs Laboratory"

28. A copy was also forwarded to the Drugs Controller General (I), Dte. General of Health Services, FDA Bhawan, New Delhi, for information.

29. The petitioner had given a reply on 18.08.2017 for the show cause notice dated 02.08.2017. In the reply they had stated that the impugned drugs are sensitive drugs and they have to be stored below 30^0 temperature. It was stated that deterioration could have taken place owing to improper storage. It was also stated that proper testing procedure had not been adopted.

30. A reply was also given for the report given in Form – 13. This reply was given on 12.10.2017. In the reply, it had been stated as follows:

> ".....
> We can file a miscellaneous application in the local court for sending the sample to the Director CDL, Kolkata for retesting under section 25(4) of the Drugs and Cosmetics Act as the undersigned is a senior citizen and cannot take such long joinery to Chennai. CDSCO, Baddi had conducted detailed investigation into this case and it was found that we manufactured the drug very much of standard quality, but some thing had gone wrong due to improper storage. Control sample was also tested in presence of the investigating officer.
>
> It seems that the Government Analyst at CDL, Kolkata has not used proper method of analysis and did not compare properly with reference standard and its impurity which is being asked for later on. Also please enquire about the storage condition of the impugned drug from Dec 2016 to May 2017. Kindly examine the matter thoroughly and inform us accordingly to enable us to proceed further into this matter."

31. Thereafter, on 07.12.2017, the order of blacklisting of the petitioner firm for a period of 5 years from 05.08.2017 to 04.08.2022 had been passed. The second order was passed on 12.02.2017 and again, the petitioner was blacklisted for a period of 5 years from 05.02.2017 to 12.02.2022 for supply of spurious drugs namely Carbimazole Tablets IP 5mg (D.Code:270). The petitioner then filed an appeal under Rule 23 of the Tender document before the 3rd respondent. As stated, the petitioner had to file Writ Petitions seeking disposal of the appeals. Finally, the impugned order was passed by the Secretary to Government,

Health and Family Welfare (H2) Department on 26.06.2019 in Letter No.46953/H2/2017 - 6. In the impugned order, after stating the facts, it had been stated as follows:

> "4. The Government have examined your appeal (the firm M/s.Jackson Laboratories Private Limited), made against the order of the Tamil Nadu Medical Services Corporation Limited, in detail along with the oral submission made by you during the personal hearing on 02.04.2019 and also with the remarks of Managing Director, Tamil Nadu Medical Services Corporation Limited and on perusal of the documents on record it has been observed that your company accepted to supply the drug as per the specification and packing specified in the tender floated by Tamil Nadu Medical Services Corporation Limited. Having accepted the condition, your firm has failed to supply the same to the satisfaction of the quality control of the Central Drugs Laboratory. It appears that there is no merit in the appeal preferred by the drugs supplying firm M/s.Jackson Laboratories Private Limited and the Government proposes to uphold the orders of Tamil Nadu Medical Services Corporation Limited blacklisting your firm for supply of spurious drugs and to reject you (M/s.Jackson Laboratories Private Limited, Amritsar) appeal fourth cited as devoid of merits and orders accordingly.
>
> Yours faithfully,
> Secretary to Government"

32. A perusal of the impugned order shows that a personal hearing had been afforded on 02.04.2019 and thereafter, the records had been perused and thereafter, holding that the petitioner had accepted the tender conditions, and had failed to supply drugs to the satisfaction of the quality control of the Central Drugs Laboratory, the appeal was dismissed. This order has been challenged in the present Writ Petition. It is trite to point out that a decision taken in an Administrative Order, can be rarely examined by the Court unless there is a procedural violation.

33. The learned Senior Counsel for the petitioner argued that under the provisions of the Drugs and Cosmetics Act, 1940, on testing of a particular drug, a report can be given that either the drug is substandard or the drug is spurious. In the instant case, the learned Senior Counsel stated that a finding

has been returned that the drugs supplied by the petitioner are both substandard and spurious. It was also pointed out by the learned Senior Counsel that proper opportunity was not granted to further test the quality of the drug in the Central Laboratory at Kolkata.

34. A Division Bench of the Delhi High Court in LPA.No.633 of 2010, Ind-Swift Ltd., Vs. Union of India & Others, by judgment dated 16.12.2011, with respect to similar contentions raised as in this case, stated that it has to be examined whether there was any material irregularity in the decision regarding the process or the impugned decision is irrational, unreasonable or arbitrary.

35. It was stated that the primary aspect to be examined is whether there is procedural violation of the provision of the Act. A perusal of the report shows that the drugs have been examined with respect to each batch of sample and specific findings have been given with respect to the results. They have been extracted above.

36. It is seen that one of the results showed that the drugs were spurious in nature. It was tested again. It was then held to be not of standard quality. The drugs were also tested at Central Laboratory, Kolkata, which again gave a result that the drugs were not of standard quality. Two show cause notices were issued to the petitioner. Personal hearing also granted to the petitioner. In the first instance, the petitioner did not take up the opportunity to attend personal hearing, claiming that he could not travel from Punjab to Chennai. However, the impugned order contains the explanations which have been considered and only thereafter, the order blacklisting the petitioner had been passed.

37. In Montecarlo Limited V. National Thermal Power Corporation Limited, (2016) 15 Supreme Court Cases 272, in which it had been stated as follows:

> "19. In Sterling Computers Ltd. v. M&N Publications Ltd. (1993) 1 SCC 445] , the Court has held that under some special circumstances a discretion has to be conceded to the authorities who have to enter into contract giving them liberty to assess the overall situation for purpose of taking a decision as to whom the contract be awarded and at what terms. It has also been observed that by way of judicial review the Court cannot examine the details of the terms of the contract which have been

entered into by the public bodies or the State. Courts have inherent limitations on the scope of any such enquiry.

20. In Tata Cellular v. Union of India, (1994) 6 SCC 651 a three-Judge Bench after referring to earlier decisions culled out certain principles, namely, (a) the modern trend points to judicial restraint in administrative action, (b) the Court does not sit as a court of appeal but merely reviews the manner in which the decision was made, (c) the Court does not have the expertise to correct the administrative decision. If a review of the administrative decision is permitted it will be substituting its own decision, without the necessary expertise which itself may be fallible, and (d) the Government must have freedom of contract and that permits a fair play in the joints as a necessary concomitant for an administrative body functioning in an administrative sphere or quasi-administrative sphere. Hence, the Court has laid down that the decision must not only be tested by the application of the Wednesbury principle [Associated Provincial Picture Houses Ltd. v. Wednesbury Corpn., (1948) 1 KB 223 (CA)] of reasonableness (including its other facts pointed out above) but must be free from arbitrariness not affected by bias or actuated by mala fides."

38. In the instant case, the test reports indicate that the tablets supplied by the petitioner were not of standard quality. The report that they were spurious has been superseded by the report from the Central Drugs Laboratory, Kolkatta. In view of this fact, I set aside the portion of the order by which the petitioner firm has been blacklisted. The particular tablets, namely, Carbimazole Tablets IP 5mg (D.Code:270) manufactured by the petitioner is blacklisted for a period of 5 years, and that portion of the impugned order is confirmed.

39. I therefore hold that the impugned order is set aside in so far the portion blacklisting the petitioner company for a period of 5 years. However, the particular drug, Carbimazole Tablets IP 5 mg (D.Code:270) alone is banned for a period of 5 years.

40. In the result, the Writ Petition is partly allowed. No order as to costs. Consequently, the connected Writ Miscellaneous Petition is closed.

Sd/-
Assistant Registrar(CS III)

//True Copy//

Sub Assistant Registrar

To,

1.The Secretary to Government
Health and Family Welfare (H2) Department,
Secretariat,
Chennai - 600 009.

2.The Chairman
Tamil Nadu Medical Services Corporation Ltd
Board-Cum-Principal Secretary,
Department of Health and Family Welfare,
Government of Tamil Nadu,
Chennai - 600 008.

3.Tamil Nadu Medical Services Corporation Ltd.,
(A Government of Tamil Nadu undertaking)
Represented by its Managing Director,
No.147, Pantheon Road, 2nd Floor,
Egmore, Chennai - 600 008.

4.General Manager (Drugs)
Tamil Nadu Medical Services Corporation Ltd,
No.147, Pantheon Road, 2nd Floor,
Egmore, Chennai - 600 008.

+1cc to Mr.P.Ramesh Kumar, Advocate Sr.17913

W.P.No.25770 of 2019

ssi[co]
srg 03/03/2020