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(2019) 07 MP CK 0067

In the Madhya Pradesh High Court

Case No : Writ Petition No. 5994 Of 2019

M/S Celon Laboratories Private Limited — APPELLANT

Vs

State Of Madhya Pradesh — RESPONDENT

Date of Decision : 04-07-2019

Acts Referred:
Constitution Of India, 1950 — Article 226
Drugs And Cosmetics Act, 1940 — Section 23, 19(2)(b)

Citation : (2019) 07 MP CK 0067

Hon'ble Judges : Subodh Abhyankar, J

Bench : Single Bench

Advocate : Naman Nagrath, Anvesh Shrivastava, Rajbahoran Singh, Rohit Jain

Final Decision : Allowed

Judgement

1. The present petition has been filed by the petitioner â?" M/s Celon Laboratories Pvt. Ltd. â?" under Article 226 of the Constitution of India against

the order dated 6.12.2018 (Annexure P-16) passed by the respondent No.2 â?" Commissioner, Department of Health and Family Welfare, Bhopal on

an appeal preferred by the petitioner against the order dated 13.4.2018 (Annexure P-11) passed by the respondents No.3 and 4 whereby the

petitioner-Company has been blacklisted for a period of three years and their rate-contract has been suspended.

2. The case of the petitioner is that it is in the business of manufacturing of drugs and as many as 100 pharmaceutical products are being

manufactured by them. The petitioner Company was incorporated in the year 2001. In the course of its business, the petitioner-Company was

awarded rate-contract in pursuance of the Tender No.89 issued by M.P. Public Health Services Corporation Ltd. for the supply of certain

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pharmaceutical products to the various Government hospitals across the State of Madhya Pradesh. The petitioner was to sup?ply a dru?g called as

Dobutamine Injection USP and the value of the supply was more than Rs.24.00 Lac, and an agreement in this behalf was entered into between the

parties on 29.7.2016.

3. It is the further case of the petitioner that the aforesaid drugs are kept in a vial and are stored in a temperature ranging from 15 C to 30 C and on

the label attached to the vial it is specifically mentioned that â??this injunction should not be used if it contains visible particulate matterâ?. The case

of the petitioner is that on 21.7.2017, a show cause notice was served on the petitioner-Company wherein it was stated that at three places, four

batches of injection were found to be NSQ (Not of Standard Quality). The contention of the petitioner is that the aforesaid samples viz., two samples

from District Morena on 16.6.2017, one sample from Dindori on 22.7.2017 and another sample was taken from Mandsaur on 28.6.2017 by the

respondent in utter violation of the agreement between the parties and above all, before declaring the same to be unfit for consumption, even a

chemical test was not carried out and the opinion has been given only by visible inspection of the vial.

4. The show cause notice was issued on the ground that there is a complaint of change of colour of the aforesaid injections. The complaints were

made by the Civil Surgeon cum Chief Hospital Superintendent, District Morena and Dindori and the Chief Medical and Health Officer, Mandsaur.

Thus, stating that since the change of colour is a serious complaint, the notice was issued to the petitioner-Company as to why a disciplinary action be

not taken against it.

5. A reply to the aforesaid notice was submitted by the petitioner on 25.7.2017 (Annexure P-8) wherein it is stated that the product molecule is

photosensitive in nature and if the product is kept out of carton for a longer time it may change the colour but potency-wise and the quality-wise the

product is unchanged. Along with the reply, the reports of the Government approved Laboratory were also submitted by the petitioner of the same

batches which were found by the respondent as NSQ. However, after the test reports were received by the respondents from the Government

Laboratory, another show cause notice was issued to the petitioner on 20.2.2018

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(Annexure P-9) asking the petitioner as to why the petitioner-

Company be not blacklisted for a period of three years. Along with the notice, the test reports of the drugs were also enclosed by the respondents

wherein it was mentioned that, â??the sample fails to comply with the requirement in respect of descriptionâ? and under the â??descriptionâ?? head,

it was mentioned that the â??brown coloured solution containing particles that can be observed on visual inspection by the unaided eyeâ?. Thus,

admittedly the test was conducted by the respondents by visual inspection only and no chemical test was carried out.

6. The aforesaid show cause notice was also replied to by the petitioner-Company on 26.2.2018 vide Annexure P-10 wherein, among other grounds, it

was specifically stated that till date they have not received any complaint regarding the quality of the product from any Civil Surgeon or Chief Medical

and Health Officer of any location. A supplementary submission was also submitted by the petitioner to the said notice. On such replies, the final order

was passed on 13.4.2018 (Annexure P-11) by the respondents No.3 and 4, which is also under challenge in this petition.

7. The aforesaid order was initially challenged by the petitioner-Company in an appeal before the Corporation itself which was partly allowed on

19.6.2018 by the Chief General Manager (Technical), which has been approved by the Managing Director thereby only debarring the particular drug

i.e. Dobutamine Injection USP which was the subject matter of the test. However, when the order was again challenged by the petitioner-Company

before this Court in W.P. No.15366/2018, this Court vide its order dated 5.9.2018 (Annexure P-14) held that the petitioner-Company is at liberty to file

an appeal before the Commissioner (Health), who is the appropriate and competent Authority according to the tender conditions. Thus, another appeal

was preferred by the petitioner-Company before the respondent No.2 on 12.9.2018, which was decided by the respondent No.2 â?" Commissioner

vide impugned order dated 6.12.2018 (Annexure P-16) whereby the petitionerâ?? s appeal was dismissed and the order dated 13.4.2018 (Annexure

P-11) blacklisting the petitioner-Company and suspension of rate-contract has been affirmed.

8. Learned counsel for the petitioner has assailed the aforesaid order mainly on the ground that the samples of the Dobutamine Injection USP were

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not obtained by the respondents as provided in the â??procedure for blacklistingâ?? part of the agreement/tender document. Learned counsel has

also drawn attention of this Court to Clause 6 of the Procedure for Blacklisting contained in Annexure XI at internal page No.48 of tender document,

which deals with the blacklisting for quality failure and provides that if the sample fails in quality test and report is received certifying that sample is

â??Not of Standard Qualityâ??, one more sample shall be drawn from the same batch and to be sent to Government Laboratory for quality testing

and on confirmation of the test result by the second Laboratory, Firm will be blacklisted as per the other terms. It is further provided that in case the

second report is contradictory to the first report, the Government Lab report will be final and if the sample has been tested by the Government Lab at

any stage, its report will be conclusive and final unless challenged as per provisions of Drugs & Cosmetics Act, 1940.

9. Thus, it is submitted that in the present case, samples were not taken by the respondents in the presence of the employees of the petitioner-

Company and a copy of the sample was also not handed over to the petitioner-Company. It is further submitted that otherwise also it was incumbent

upon the respondents to get samples tested as provided in the tender documents but none of these procedures were followed and in fact, even

according to Governement Labâ??s test reports, the samples were only visually examined in the laboratory and no chemical test was carried out.

Thus, according to learned counsel for the petitioner only on this ground the impugned orders are liable to be quashed.

10. Learned counsel for the petitioner has further submitted that even according to the tender document, the defects as pointed out by the respondents

were minor and were falling in category â??Câ? (Minor defect category) as provided in internal page 52 of the tender document. Sub-clause (iv) and

Clause (v) provide that â??clear liquid preparations showing sedimentationâ? and â??change in colour of the formulationâ? would be considered as

minor defect. Learned counsel has further submitted that so far as visual inspection and quality of product is concerned, it is specifically mentioned on

the label of the vial itself that it has to be kept out of the Sunlight. Thus, since the samples were drawn by the respondents in the absence of any of the

officers of the Company and without following the due procedure as prescribed in the contract, it cannot be said that the same were kept in proper

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condition throughout as the samples were drawn on 16.6.2017 from Morena, on 4.7.2017 from Mandsaur and on 31.7.2017 from Dindori whereas the

test report reveals that same were conducted only on 27.1.2018, thus, it is submitted that for a period of around six or seven months, how the samples

were kept in the custody of the respondents is not known and their mishandling cannot be ruled out. It is submitted that in the meanwhile, the entire

Dobutamine Injection USP contained in the respective batches in question and which were supplied to the Government were utilised by the respective

hospitals without any complaint.

11. Learned counsel has further submitted that the work order has been executed in its entirety as the said drug was supplied by the petitioner-

Company soon after they entered into an agreement on 29.7.2016 (Annexure P-4) in which it is provided that entire supply has to be made within a

maximum period of 60 days. Thus, from the month of September, 2016 till July, 2017 when the first sample was obtained, the drug was consumed in

the Government Hospitals and there was no complaint made by any of the concerned authorities about the quality of the product..

12. Learned counsel for the petitioner has also relied upon a judgment rendered by a coordinate bench of this Court in the case of M/s Impha Labs

Indore and others v. State of M.P. (1990 SCC Online MP 264) to submit that in absence of analysis of the particles found in the medicine it cannot be

held that they were of extraneous substance and not particulate matter of the contents of the medicine coming into existence during storage

subsequent to its manufacture.

13. On the other hand, learned counsel for the respondent Nos.1, 2 and 5/State has opposed the prayer and has submitted that no case for interference

is made out as the learned Commissioner has passed the order after due consideration of the material placed on record. It is further submitted that no

sooner the Government came to know about such defect in the batches of the aforesaid drug, a notice was immediately sent to all the hospitals on

4.7.2017 directing them not to use the aforesaid drug. So far as the sampling of the drug is concerned, learned counsel has submitted that although no

panchnama has been prepared regarding the same but this objection has not been taken by the petitioner in their initial reply. Learned counsel has

further submitted that looking to the fact that as many as four samples were

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found to be â??not of standard qualityâ? i.e. NSQ, the respondents had

no option but to blacklist the petitioner-Company as provided in Annexure-XI appended to the tender document (Annexure P-3). It is submitted that

even if the defect is minor in nature, since the samples were found to be â??not of standard qualityâ?? in as many as three batches, the action has

been taken against the petitioner-Company, as provided under Clause 8 of the tender document contained in internal page 52 thereof. Thus, it is

submitted that the petition being devoid of merit, is liable to be dismissed.

14. Shri Rohit Jain, learned counsel for the respondents No.3 and 4 has reiterated the submissions made by the learned counsel for the respondents-

State. He has submitted that while passing the impugned order, the due procedure has been adopted by the respondents and an adequate opportunity

of hearing has been provided to the petitioner and since the petitioner has not been able to make out any case for revocation of the order of

blacklisting, appellate Authority has also affirmed the same. Thus, it is submitted that the petition deserves to be dismissed.

15. Heard learned counsel for the parties and perused the record.

16. From the record, this Court finds that admittedly the samples of the Dobutamine Injection USP were taken on 16.6.2017, 4.7.2017 and 31.7.2017.

In the entire record, no document has been filed either by the petitioner or the respondents regarding the manner in which such samples were

obtained. So far as the sampling of the drug is concerned, reference may be had to Clauses 3 to 6 of the tender document (at page 60 of the writ

petition), which reads, thus:

â??BLACKLISTING FOR QUALITY FAILURE,

3. Each and every batch of drugs/medicines supplied by the suppliers shall be subjected to quality test by the laboratories selected/empaneled by

Tender Inviting Authority.

4. The samples are collected from the Stores from each batch of supply of the same drugs and after eliminating the common batch, samples shall be

taken in random, decoded and to be sent to the empanelled testing laboratories for testing the quality of drugs.

5. If such sample passes quality test in all respects, ordering authority will instruct its store to issue such items of drugs to various hospitals/Institutions.

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6. 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. On confirmation of the test result by the second laboratory,

firm will be black listed as per terms. In case when the second report is contradictory to the first report, the Govt. Lab report will be final and if the

sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final unless challenged as per provisions of Drugs & Cosmetics

Act, 1940.â??

17. From the pleadings, especially the reply submitted by the respondent Nos.1, 2 and 5, which is only one page affidavit filed by the Officer-in-charge

of the case, it is apparent that the aforesaid procedure has not been followed by the respondents while obtaining the samples. However, during the

course of argument, learned counsel for the respondents-State has submitted that since all the officers of the State are well qualified, hence, it has to

be presumed that the samples were obtained as provided under the provisions of the tender document and were kept in the safe custody and in ideal

condition. This Court finds the argument rather naive and bereft of substance.

18. The sample reports have also been placed on record as Annexure P-9. The relevant extracts of the same read as under:-

â??DRUGS TESTING LABORATORY FOOD AND DRUGS

ADMINSITRATION M.P.

IDGAH HILLS BHOPAL, 462001

No.29 N Dated 27/1/18

FORM-13

(See rule 46)

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7. Result of test or analysis with protocol of Test or analysis applied.

is given below

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in the Drugs & Cosmetics Act, 1940 and rules

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there under for the reason given below.

Reason.:- The sample fails to comply with the requirement in respect of description.

*** *** ***

Container: Colourless vial placed in a carton. Such three vials are received.

*** *** ***

Description: Brown coloured solution containing particles that can be observed on visual inspection by the unaided eye.

(Requirement: Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can

observed on visual inspection by the unaided eye).â??

19. Admittedly, in the aforesaid test report it is mentioned that the samples are not of standard quality, as defined under the Drugs and Cosmetic Act,

1940 and in Annexure XI appended to the tender document which relates to procedure for blacklisting in para 6, which provides for the sampling

under the blacklisting for quality failure, it is again provided that the provisions of the Drugs and Cosmetic Act, 1940 would be applicable to the

aforesaid sampling process. A reference may also be had to Section 23 of the Drugs and Cosmetics Act, 1940, which provides for the procedure for

inspectors as under:-

â??23. Procedure of Inspectors.â?" (1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price

thereof and may require a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused or where the Inspector seizes the stock of any drug or cosmetic under clause (c) of

section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the

prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample

into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so

sealed and marked:

Provided that where the sample is taken from premises whereon the drug or

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cosmetic is being manufactured, it shall be necessary to divide the sample

into three portions only:

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector

may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may

be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall

retain the remainder and dispose of the same as follows:-

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic; and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(5) Where an Inspector takes any action under clause (c) of section 22,â?

(a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of section 18 and, if it is ascertained

that the drug or cosmetic does not so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as

may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody

thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the

drug or cosmetic, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall,

as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.â??

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20. This Court finds force in the contention raised by the learned counsel for the petitioner that the valuable right of the petitioner to get the sample

examined from a Government Laboratory has been violated as no part of the sample was provided to the petitioner. The record also reveals that only

one sample was obtained by the respondents whereas clause 6 as reproduced above clearly prescribes testing by two samples. This court also finds

that along with the reply to the show cause notice issued to the petitioner, which is marked as Annexure P-8, the petitioner had also enclosed the test

report of the samples of relevant batches from a Government approved Laboratory in which the result has been given that â??free from visible

particles when seen against diffused light with unaided eyesâ? and the opinion has been given that the aforesaid samples are of standard quality as

defined in the Act and the Rules made thereunder. These documents have also not been denied by the respondents.

21. This Court also finds that the petitioner in their rejoinder has also stated that the drugs of the batches in question which was supplied to the other

hospitals of the respondent has already been utilised in those hospitals and not a single complaint has been received by the petitioner-Company. No

counter affidavit to this rejoinder has been filed by the respondents-State and in fact, and instead, as already observed above only an affidavit has been

filed by them of the Officer-in-Charge of the Drug Testing Laboratory, Bhopal without any supporting documents.

22. Still further, this Court in M/s Impha Labs Indore (supra) has held as under:-:-

â??28. On a careful consideration of the arguments and the relevant provisions of the Act, I am of the view that the contention that in the absence of

analysis of the particles found in the medicine it cannot be held that they were of extraneous substance and not particulate matter of the contents of

the medicine coming into existence during storage subsequent to its manufacture must be accepted. Further in view of the provisions in Section 19(2)

(b) of the Act, even on the assumption that the particles were of extraneous matter the drug cannot in the absence of allegation of awareness of the

inter-mixture, be said to be sub-standard merely on the ground of their presence therein. Absence of such allegation knocks the bottom out of the

prosecution case.â??

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(emphasis supplied)

23. In view of the above facts and circumstances of the case, this Court is satisfied that the respondents have not followed the procedure for sampling

of the drug in question as provided in the agreement itself and it appears that only one sample of each of the batches has been obtained in a casual

manner and the report has been prepared in the same casual manner. The Laboratory in question has not even cared to carry out the chemical

analysis of the sample to give a positive finding regarding the potency and standard quality whereas on the label affixed on the vial by the petitioner-

Company, as contained in Annexure P-6, a caution has been given that â??the injection should not be used if it contains visible particle matterâ?.

Thus, even while manufacturing the aforesaid drug, a word of caution has already been mentioned by the petitioner-Company on the label itself,

therefore, in the absence of due procedure being followed for initiating penal provisions of blacklisting the petitioner-Company, it cannot be said that

the petitioner-Company was at any fault in producing the aforesaid item. It is rather surprising that despite passing the adverse order against the

petitioner-Company in the present petition, the respondents/State has decided not to file a proper reply.

24. In view of the aforesaid discussion, the impugned order dated 13.4.2018 (Annexure P-11) and order dated 6.12.2018 (Annexure P-16) cannot be

sustained and are hereby quashed.

25. Resultantly, the writ petition stands allowed.

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