



Crl.O.P.No.13904 of 2023

In the High Court of Judicature at Madras

Reserved on : 20.7.2023	Delivered on : 24.7.2023
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Coram :

The Honourable Mr.Justice N.ANAND VENKATESH

Criminal Original Petition No.13904 of 2023
& Crl.M.P.Nos.8550 & 8551 of 2023

1.M/s.Christian Medical College,
Ida Scudder Road, Vellore,
rep.by Secretary Thiru.Solomon
Sathishkumar

2.Thiru.Solomon Sathishkmar,
Secretary of M/s.Christian
Medical College Vellore
Association, Ida Scudder
Road, Vellore.

3.Thiru.Prasad Kuruvilla Mathews,
Authorized Signatory of
M/s.Christian Medical College,
Ida Scudder Road, Vellore.
...Petitioners

Vs

The Tamil Nadu State rep.by
the Drugs Inspector,
Vellore I Range, O/o the
Assistant Director of Drugs
Control, 1/50, Thiru Vi Ka Nagar,
6th Street, Rangapuram,
Vellore-9.

...Respondent



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PETITION under Section 482 of the Criminal Procedure Code seeking to call for the records and quash the complaint and proceedings in S.T.C.No.255 of 2023 pending on the file of learned Judicial Magistrate IV, Vellore.

For Petitioners : Mr.Krishna Srinivasan, SC for
M/s.S.Ramasubramaniam &
Associates

For Respondent : Mr.A.Gopinath,
Government Advocate (Crl.Side)

ORDER

This criminal original petition has been filed seeking to quash the proceedings pending in S.T.C.No.255 of 2023 before learned Judicial Magistrate-IV, Vellore (hereinafter called the Court below).

2. The petitioners herein have been arrayed as accused Nos.1 to 3 in the complaint filed by the respondent for contravention of Sections 18(a)(i) and 18(c) of the Drugs and Cosmetics Act, 1940 (for brevity, the Act) read with Rule 74 of the Drugs Rules, 1945 (for short, the Rules) read with Condition No.3 of the Conditions of Licence stated in Form 25, punishable under Section 27(d) of the Act.

3. The brief facts leading to filing of this petition are stated as



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hereunder :

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(i) The Drugs Inspector collected a sample of Glycerin Oral Solution U.S.P. 50% manufactured by the Christian Medical College (for short, the CMC), Vellore for analysis on 25.6.2021. The samples drawn were sent for analysis to the Drugs Testing Laboratory, Chennai on the same day. A report dated 30.7.2021 was received from the State Laboratory wherein it was found that the sample did not conform to the U.S.P. specification with respect to pH. In other words, the Glycerin Oral Solution was supposed to have U.S.P. between 5.5 and 7.5 whereas the U.S.P. found in the sample was 8.643.

(ii) A show cause notice dated 03.8.2021 was issued to the CMC, Vellore calling for an explanation. On receipt of the same, the explanation was given by the CMC, Vellore on the same day. Thereafter, yet another show cause notice dated 10.8.2021 was issued. In the second show cause notice, apart from the contravention of Section 18(a)(i) of the Act, the contravention under Section 18(c) of the Act was also pointed out on the ground that the drug was manufactured without a valid product permission and the explanation was called for from the CMC, Vellore, which gave a reply



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dated 12.8.2021. Even thereafter, two more replies were given on 13.8.2021 and 16.8.2021.

(iii) The third show cause notice dated 22.11.2021 came to be issued by the respondent to the CMC, Vellore calling for explanation within 15 days. Again, a reply was sent on 02.12.2021. A personal hearing was also conducted by the Director of Drugs Control and the explanation was given.

(iv) Ultimately, the last show cause memo, which can be taken to be the composite show cause notice, dated 20.12.2021 was issued calling for explanation from the CMC, Vellore. A reply dated 28.12.2021 was sent by the Director of the CMC, Vellore wherein the In-House Quality Control Analysis report was pointed out, which showed that the pH level was well within the parameter at 7.36. In view of the same, a request was made for re-testing the sample in the Central Drugs Laboratory.

(v) Ultimately, the complaint came to be filed before the Court below 04.1.2023 for the contravention of the provisions of the Act, the Rules and the Conditions of Licence. The said complaint was taken cognizance by the Court below and summons were issued to the petitioners. Aggrieved by the same, the above criminal original



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petition has been filed before this Court.

4. Heard the learned Senior Counsel appearing on behalf of the petitioners and the learned Government Advocate (Criminal Side) appearing for the respondent.

5. The first ground raised by the learned Senior Counsel appearing on behalf of the petitioners is that the petitioners have been deprived of their valuable right conferred under Section 25(4) of the Act to have the second sample re-analysed from the Central Drugs Laboratory. According to him, the samples were drawn on 25.6.2021 and the expiry date of the drug was 19.1.2023. It was further submitted that the petitioners had conducted their in-house quality control test, in which, it was found that the pH level was well within the parameter, that therefore, a request was made while giving the reply to the show cause memo dated 20.12.2021 to send the drug for re-testing in the Central Drugs Laboratory, that however, the sample was sent to the Central Drugs Laboratory only on 29.12.2022, that the complaint was filed on 04.1.2023, that by the time the summons were served on the petitioners, the period had expired for the drug on 19.1.2023 and that the petitioners were



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deprived of their right of sending the second sample for re-analysis.

6. Per contra, the learned Government Advocate (Criminal Side) appearing for the respondent submitted that the sample was sent for re-analysis to the Central Drugs Laboratory after filing of a petition by the respondent herein before the Court below on 29.12.2022 and that the report of the Central Drugs Laboratory also confirmed the fact that the drug sample did not pass the test as the pH level was found to be 7.81. Therefore, he would further submit that the right given to the petitioners for re-analysis has not been deprived.

7. This Court has carefully considered the submissions made by the learned counsel on either side and perused the materials available on record.

8. Section 23 of the Act prescribes the procedure to be followed by the Drug Inspector, who takes the sample of the drug. For the purpose of this case, it would suffice to take note of Section 23(4) of the Act, which is extracted as hereunder :

"23. Procedure of Inspectors :

(1)

(2)



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(3)

(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."

9. It is clear from the above that the Inspector is expected to keep one portion of the sample and the other portion should be disposed of by sending a part of it forthwith to the Government Analyst for test and the second part should be produced to the court, before which, the proceedings are instituted.

10. In the instant case, the first part of the drug was sent for analysis to the State Laboratory on 25.6.2021 itself. The other part was sent to the Court below only on 29.12.2022 and thereafter, that part was sent for analysis to the Central Drugs Laboratory. It is clear



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from the records that even the Central Drugs Laboratory found that the pH level of the drug was found to be 7.81 and it was also opined that the drug was not of a standard quality. Both the reports from the State Laboratory and the Central Drugs Laboratory show that the pH value of the drug was not within the parameter.

11. The learned Senior Counsel appearing on behalf of the petitioners submitted that there was a delay in sending the drug for analysis to the Central Drugs Laboratory and that the same should have been sent at the earliest.

12. In the considered view of this Court, the said submission was made by the learned Senior Counsel appearing on behalf of the petitioners on the premise that Section 23(4)(ii) of the Act mandates the second part of the sample to be produced before the court immediately. A plain reading of the provision does not mandate the sample to be sent forthwith as is found in Section 23(4)(i) of the Act. The provision only states that the second part should be produced to the court, before which, the proceedings are instituted in respect of the drug. The provision does not warrant the drug to be sent



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immediately and no time limit has been prescribed.

13. In any case, the Central Drugs Laboratory tested the sample well within the expiry date and the drug was found to be not of standard quality. There is no reason for this Court to disregard the report given by the Central Drugs Laboratory at this stage. The petitioners are also not deprived of the right of re-analysis of the sample by the Central Drugs Laboratory since the respondent had initiated such a process and received the report from the Central Drugs Laboratory.

14. Section 25 of the Act deals with reports of Government Analysts. For proper appreciation, Sub-Sections (3) and (4) of Section 25 of the Act are extracted as hereunder :

"25.

(1).....

(2).....

(3) *Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of 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*



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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 contravention of the report.

(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 contravention 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."

15. The report given by the Government Analyst becomes final unless the person, from whom the sample was taken, has, within 28 days of the receipt of the report, notified in writing that he intends to adduce evidence in contravention of the report. If the sample has already been tested or analysed in the Central Drugs Laboratory, there is no occasion for the person concerned to express his intention of adducing evidence in contravention of the Government Analyst's



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report to once again send for re-analysis to the Central Drugs Laboratory.

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16. In the instant case, if the respondent had not sent the sample for analysis to the Central Drugs Laboratory and by the time the petitioners make such a request before the Court below the life of the drug expires, then it can be held that the petitioners are deprived of their valuable right of re-analysis. The report of the Central Drugs Laboratory is already available and such a report was prepared after analysing the drug within its life period and therefore, it cannot be held that the petitioners were deprived of their right to send the drug for analysis by the Central Drugs Laboratory after the complaint was filed by the respondent.

17. The judgments of the Apex Court relied upon by the learned Senior Counsel appearing on behalf of the petitioners will not apply to the facts of the present case.

18. In the first judgment that was relied upon in the case of ***Medicamen Biotech Ltd. Vs. Drug Inspector [reported in 2008]***



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(7) SCC 196], the drug was not sent for re-analysis and by the time the complaint was filed, the shelf life of the drug had expired. Therefore, it was held that the right given to the person under Section 25(3) and (4) of the Act was denied.

19. The second judgment that was relied upon in the case of ***State of Haryana Vs. Unique Farmaid (P) Ltd. [reported in 1999 (8) SCC 190]*** is also a case where the accused person lost the right of re-analysis of the drug since, by the time he received the summons from the court concerned, the shelf life of the drug had expired.

20. The third judgment that was relied upon in the case of ***Medipol Pharmaceutical (India) (P) Ltd. Vs. Post Graduate Institute of Medical Education & Research [reported in 2021 (11) SCC 339]*** is a case where there was an unexplained delay in sending the sample for testing and on that ground, it was held that the valuable right granted under Section 25 of the Act was denied.

21. The next ground raised by the learned Senior Counsel



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appearing on behalf of the petitioners is that petitioner Nos.2 and 3 have been arrayed as accused Nos.2 and 3 without any specific allegation attributed against them.

22. In the considered view of this Court, the second petitioner (A2) is the Secretary of M/s.Christian Medical College Vellore Association and the by-laws of the association make it clear that the Secretary is the person, who is in charge of the association and the legal responsibility is upon him.

23. In so far as the third petitioner (A3) is concerned, he is the authorized signatory of the CMC, Vellore and he was the one, who signed Form-17 and the subsequent reply that was submitted on behalf of the CMC, Vellore. Therefore, it cannot be held that he is not involved in the conduct of business. Prima facie, this Court does not find any contravention of Section 34 of the Act.

24. In the light of the above discussions, this Court does not find any ground to quash the proceedings pending before the Court below. It is left open to the petitioners to raise all the grounds before



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the Court below, which shall decide the case uninfluenced in any manner by any of the observations made in this order, on merits and in accordance with law.



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25. In the result, the above criminal original petition stands dismissed. Consequently, the connected Crl.M.Ps. are also dismissed.

24.7.2023

Index : Yes
Neutral Citation : Yes
Speaking Order : Yes

To

- 1.The Drugs Inspector, Vellore I Range, O/o the Assistant Director of Drugs Control, 1/50, Thiru Vi Ka Nagar, 6th Street, Rangapuram, Vellore-9.
- 2.The Judicial Magistrate No.4, Vellore.
- 3.The Public Prosecutor, High Court, Madras

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N.ANAND VENKATESH,J

RS

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