IN THE HIGH COURT OF JUDICATURE AT BOMBAY
NAGPUR BENCH AT NAGPUR

CRIMINAL WRIT PETITION NO.479/2023

M/s. Unison Pharmaceutical Pvt. Ltd.
r/o P No. 124, EPIP Industrial Estate,
Jharmajri Phase No.I, Baddi, Dist.
Himachal Pradesh, through Authorised
Signatory, Shri Prem Nath, age major,
Occ. Service, r/o Plot No. 791, Ind.
Area, PH-I, Chandigarh, State Haryana .....PETITIONER

...V E R S U S...

1. State of Maharashtra through
Drug Inspector, P. R. Ramteke,
age 42 years, Occ. Drug Inspector,
r/o Office of Assistant Commissioner,
Food and Drug Administration (M.S.)
Shrimati Gitabai Wanjari Building,
Takiya Ward, Bhandara.

2. Commissioner, Food & Drug
Administration, M. S. Survey, No.34,
Bandra, Mumbai. ...RESPONDENTS

Ms Rashmi Kulkarni (Hardas), Advocate with Mr. A. M. Kukday, Advocates for petitioner.
Mrs. M. H. Deshmukh, A.P.P. for respondent

CORAM:- ANIL L. PANSARE, J.
DATED :- 03.10.2023

P.C.

The petitioner shall add "Joint Commissioner (Headquarters) and Controlling Authority, Food and Drug Administration, Maharashtra, Mumbai" as party – respondent no.3, within two working days.

Learned A.P.P. appears for the newly added respondent no.3.

2. Having perused the complaint, there are some discrepancies, which require clarification from the complainant and his predecessor as also the respondent no.3 – Joint Commissioner (Headquarters) and Controlling Authority, Food and Drug Administration, Maharashtra, Mumbai.

3. Following seven persons have been arrayed as accused in the complaint lodged by respondent no.1 – the complainant.

1) Mr. Premnath
Son of J.B. Singh
General Manager of M/s. Unison Pharmaceutical
P. No. 124, EPIP Industrial Estate
Jharmajri, Phase I, Baddi
Himachal Pradesh

2) Mr. Arun Kumar Sidhwani
Competent Technical Staff for Manufacture
M/s. Unison Pharmaceutical
P. No. 124, EPIP Industrial Estate
Jharmajri, Phase I, Baddi
Himachal Pradesh

3) Mr. Amit Sharma
Competent Technical Staff for Manufacturing
M/s. Unison Pharmaceutical
P. No. 124, EPIP Industrial Estate
Jharmajri, Phase I, Baddi
Himachal Pradesh

4) Mr. Ravindar Singh
Competent Technical Staff for Manufacturing
M/s. Unison Pharmaceutical
P. No. 124, EPIP Industrial Estate
Jharmajri, Phase I, Baddi
Himachal Pradesh

5) M/s. Unison Pharmaceutical
P. No. 124, EPIP Industrial Estate
Jharmajri, Phase I, Baddi, Himachal Pradesh

6) Mr. Ashish Tripathi

Incharge and Responsible Person
M/s. DM Pharma (Mkt.) Pvt. Ltd.
Khewat No.313, Khatuni No.441,
Near Gurdwara, Village Maloya,
Chandigarh

7) Mr. Azizurrab Khurshid Ahmad Sayyad
Proprietor and Competent Person of
M/s. Vidarbha Medimart and General Stores,
T.B. Toli Masjid, Vidya Nagar, Lohiya Ward,
Gondia, Tah. Gondia, Dist. Gondia

4. However, in the prayer clause, action has been sought only against accused nos. 1 to 5. The complainant shall explain why has he arrayed accused nos.6 and 7 when the action is sought only against first five accused.

5. As per the complaint, the Drug Inspector, namely Mr. M. V. Gotmare visited accused no.7 on 26.08.2016 and has drawn sample of Mario CV Dry Syrup having manufacturing date as February-2017, in four portions into two bottles of 30 ml.

Complainant Mr.P.R. Ramteke as also Drug Inspector Mr. M. V. Gotmare, shall explain as to how sample of the drug manufactured in February-2017 has been collected in August-2016?

6. Sub Section (3) of Section 23 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the “Act of 1940"), provides that where an Inspector takes sample of drugs for the purpose of its analysis, he has to intimate such purpose in writing, in the prescribed form to the person from whom he takes it

(Accused no. 7 in the present case). It further provides that the Inspector 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. The second proviso to Sub Section (3) provides 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.

In the present case, since accused no.7 was not manufacturer of the drugs, the provisions of the Act will require the Inspector to draw four samples and not three. Mr. Gotmare appears to have divided samples in 4 parts x 2 Bottle x 30 ml. Mario CV Dry Syrup. When inquired, learned A.P.P. on instructions, submits that each container of Mario CV Dry Syrup was of 30 ml.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M.V. Gotmare, shall place on record the copy of intimation of the purpose of the drug sample given to the accused no. 7 as envisaged in Sub Section (3) of Section 23 of the Act. He shall further submit a report as to whether he has permitted

accused no.7 to add his own seal and mark on the samples as also the response of the accused no.7.

7. Sub Section (1) of Section 23 of the Act provides that 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 acknowledgment therefor.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall submit a report as to whether they have complied with the aforesaid provision, if yes, the proof thereof shall be submitted.

8. The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall also submit a report as to whether the name of the manufacturer was printed on the bottle of Mario CV Dry Syrup.

At this stage, learned A.P.P., on instructions, submits that name of manufacturer was printed. Thus, Mr. Gotmare was aware of details of the manufacturer on the date when sample was drawn.

9. Section 18A of the Act provides as under:

> *"18A. Disclosure of the name of the manufacturer, etc. — Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the*

name, address and other particulars of the person from whom he acquired the drug or cosmetic."

It appears from the complaint that the accused no. 7 has procured the drugs under question from the accused no.6, who has procured it from the accused no.5 – the manufacturer.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall state the date when they have verified and confirmed that the manufacturer of the drug under question is accused no.5. They shall further submit a report as to whether the information of collecting the samples was intimated to accused no.5, if no, the reason thereof.

10. It appears that the test report from the Government Analyst has been received on or about 27.03.2018. The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall also submit a report as to whether test report was forwarded forthwith to the accused nos.5, 6 and 7. If no, reasons thereof.

11. The complaint indicates that on or about 09.04.2018, the Drug Inspector has made an inquiry under Section 18A of the Act of 1940. However, Sub Section (4) of Section 23 of the Act of 1940 provides that the third sample is to be sent to a person whose name, address and other particulars have been disclosed

under Section 18A, meaning thereby that inquiry under Section 18A is to be made at the time when the samples have been drawn and not subsequent to receipt of report.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall file a report in this regard as to why inquiry under Section 18A was not made on the date when the samples were drawn. It is reiterated here that Mr. Gotmare, on the date of drawing samples, was aware of the fact that the accused no.5 is the manufacturer because its name and address was printed on the Mario CV Dry Syrup bottle itself.

12. In the complaint, in para 16, the complainant has stated that accused no.6 vide letter dated 11.05.2017, disclosed that he has purchased drugs from accused no. 5. However, an inquiry in this regard was made by the Drug Inspector with accused no.7 on or about 09.04.2018 upon which the accused no.7 disclosed that he has purchased the drugs under question from accused no.5. In other words, accused no.7 has disclosed purchase of the drugs from accused no. 6, in April-2018. However, the accused no.6 has disclosed to the Drug Inspector in May-2017, about purchasing of drugs from accused no. 5. Its surprising how did Drug Inspector, in May 2017, inquire with accused no. 6 of his procurement of drug when his involvement was disclosed by

accused no. 7 in April, 2016.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M.V. Gotmare, shall file report in this regard as well.

13. The complainant in para 18 states that on 12.06.2018, he has visited and handed over his letter to accused no.1, the Director of accused no. 5 company and other accused along with a copy of report dated 27.03.2018 and a sealed part of drug in question.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall submit a report as to what prevented them from furnishing these details in March – 2018.

14. The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall also file report stating therein as to why one portion of sample was not handed over to the accused no.5 – Company, on the date when sample was drawn.

15. As could be seen, the report has been handed over on 12.06.2018. The expiry date of the drug was July - 2018. Sub Section (3) of Section 25 of the Act provides that upon handing over the report to the person, from whom sample was taken or the person whose name has been disclosed under Section 18A, within 28 days of the receipt of copy of report, the said person may adduce evidence in contravention to the report. Thus, the accused

nos. 5, 6 and 7 were entitled to adduce evidence in contravention to the report, one of modes of adducing evidence is to seek reanalysis of the drug through Central Drug Laboratory. The accused no.5, in fact, has made such request in terms of Section 25(4) of the Act of 1940.

16. Thereupon, on 11.07.2018, the complainant made an application before the Chief Judicial Magistrate, Gondia for depositing the sample of the drug for sending it to the Central Drug Laboratory, Kolkata in terms of Section 25 (3) of the said Act of 1940. The complaint does not indicate as to what order was passed thereon and what had happened thereafter. The copy of the test report is also not filed on record. This report, if received, would supersede the report of the Government analyst. Despite such status, the complaint has been lodged against the accused.

17. As such, in absence of report from the Central Drug Laboratory, Kolkata, the complainant could not have lodged the complaint against any accused.

The complainant Mr. P. R. Ramteke as also the Drug Inspector Mr. M. V. Gotmare, shall also file a report as to how the complaint has been lodged without obtaining report from the Central Drug Laboratory, Kolkata.

18. The Joint Commissioner (Headquarters) and Controlling Authority, Food and Drug Administration, Maharashtra, Mumbai shall also submit report as to the grounds on which he accorded sanction to prosecute seven accused.

19. The learned counsel for the petitioner has relied upon the following authorities to contend that because of aforesaid lapses and particularly for want of report of the Central Drug Laboratory, Kolkata, the prosecution could not have been lodged against the accused nos. 1 to 5.

(i) M/s. Medicamen Biotech Ltd. & Anr. Vs. Rubina Bose, Drug Inspector, reported in 2008 All MR (Cri) 1786 (SC),

(ii) State of Haryana Vs. Unique Farmaid P. Ltd. and Ors.; reported in MANU/SC/0645/1999

(iii) M. Sea Pharmaceuticals Pvt. Ltd. & Anr. .Vs. The State of Maharashtra & Anr, reported in 2018 All MR (Cri) 3946

(iv) M/s. Quixotic Healthcare & Ors. Vs. State of Maharashtra & Anr., 2020 All MR (Cri) 1880

(v) M.S. Theivendran and Ors. Vs. State of Maharashtra and Ors. Reported in MANU/MH/2594/2014

(vi) M/s. G. G. Nutritions and ors. Vs. The State of Maharashtra and another, Criminal Writ Petition No. 1659/2022, dated 24.03.2023 (Bombay High Court Bench at Aurangabad)

(vii) Lalankumar Singh & Ors. Vs. State of Maharashtra; reported in Indian Kanoon.org/doc/ 85058597/

(ix) Parenteral Drugs (India) Ltd. and Ors.Vs. The State of Maharashtra; MANU/MH/0996/2019

All these judgments indicate that the Courts have taken a consistent view that timely handing over of the reports of the drugs samples to the accused persons is of utmost importance and further that the complaint filed about a month short of expiry date of the drug and it was highly impossible to get sample tested before its expiry would deprive of the valuable right under Sections 25(3) and 25(4) of the Act of 1940 necessitating quashing of proceedings. The authorities have not learnt a lesson from the decision and continued with their casual and negligent approach and have, thus, favoured the manufacturer of the drugs. The conduct is highly deprecable.

20. In the present case as well, the discrepancies and lapses as pointed out above would render the prosecution against the accused unsustainable. Despite there being so many rulings on this point, it is surprising that the officers have not obeyed orders of the Court as one would expect them to. The present prosecution is not an exception, rather is a futile exercise for the reason that in absence of the report of the Central Drug Laboratory, Kolkata, the fate of the case is already ceased.

21. The accused persons have challenged the report of the Government Analyst. Section 25(4) of the Act of 1940 provides that the report of the Central Drugs Laboratory, Kolkata shall

supersede the report of the Government Analyst. In absence of the report of the Central Drugs Laboratory, Kolkata, the prosecution itself is not maintainable. The filing of complaint is a sheer abuse of process of law. The petitioner, therefore, has made out a case for quashing of the complaint. The complaint is accordingly quashed.

22. The petition however shall continue for compliance of the discrepancies noted by this Court and for further consideration, once the report is filed by the officers named in the body of order.

List the petition for further consideration on 17.10.2023.

(Anil L. Pansare, J.)

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