IN THE HIGH COURT OF JUDICATURE OF BOMBAY
BENCH AT AURANGABAD

CRIMINAL WRIT PETITION NO. 342 OF 2023

M/s Theon Pharmaceuticals Limited
& another Petitioners

Versus

State of Maharashtra & another Respondents

Mrs. R. S. Kulkarni, Advocate for the petitioners.
Mr. S. P. Sonpawale, APP for the respondents.

CORAM : R. M. JOSHI, J.
RESERVED ON : 30th JUNE, 2023.
PRONOUNCED ON : 11th JULY, 2023.

ORDER

1. This petition seeks quashment of RCC No. 4/2022 which is a complaint filed before the Judicial Magistrate First Class on 19th July, 2022 by the Drug Inspector for controversion of provisions of Section 18-A(i) punishable under Section 27 of Drugs and Cosmetics Act, 1940 (for short “the Act”).

2. Petitioner No. 1 is a public limited company incorporated under the Companies Act (for short ‘company’) and is engaged in the business of manufacturing and sale of several drugs and cosmetics.

It is also licence holder for manufacture of drug named “SG Flames Tablets” (Aceclofenac Paracetamol and serratiopeptidase Tablets). It is a non-pharmacopeial drug wherein the method of analysis is not prescribed but it is with the manufacturer. It is further contended that the Drug Inspector visited the premises of M/s Pharma Seva Pharmaceuticals Distributors at Aurangabad and had drawn sample of the abovementioned drug for the purpose of its analysis by issuing Form No. 17 as provided by the Act and Rules. Drug Inspector sent one sealed part of the sample to the Government Analyst, Maharashtra State Drugs Control Laboratory, Mumbai and in report dated 12th November, 2021 of Government Analyst it was opined that the sample is “not of standard quality”. Respondent claimed to have sent the report to company on 1st December, 2021 by registered post and since no response was received a reminder came to be issued on 27th December, 2021. The said reminder was replied by the petitioner by letter dated 10th January, 2022 wherein it is stated that petitioner No. 2 is the Incharge of the day to day affairs of company and is responsible for the analysis and manufacturing of the drugs of the company. It is also stated that they have analysed their control sample and have found the same to be in perfectly prescribed formulation and the test results were satisfactory. Petitioner No. 1

requested respondent to send one of the sealed sample as per Section 23 of the Act so that the same can be determined whether the same is authentic or substitute in the name of the company. Durg Inspector however, filed complaint before the Magistrate Corporation Court, Aurangabad which came to be registered as RCC No. 4/2022. It is contended that the shelf life of the said drug had expired in February 2022 and by ignoring the said fact, the learned Magistrate has issued summons mechanically against the accused.

3. Learned counsel for petitioners states that there is non-compliance of mandatory provision of the Act which has resulted into denial of the opportunity of defence to the petitioners/accused. It is submitted that it is a non-pharmacopeial drug and hence there is no prescribed method of analysis and as a result of which, the report of the Government Analyst cannot be treated as conclusive evidence. It is further submitted that the Drugs Inspector has failed to comply with the mandatory provisions of Section 23(4) of the Act and in any case, there is no sample provided to the manufacturer i.e. petitioner No. 1 herein in order to give an opportunity to challenge the said report of the Government Analyst. It is also submitted that since admittedly the sample has expired in February, 2022, it was not open

for the learned Magistrate to take cognizance of the complaint and issue summons as petitioner No. 1 is denied an opportunity to refer the sample kept with the Court to the Central Drugs Laboratory. It is contended that it is indispensable right of the accused and since there is non-compliance of this mandatory provision, prosecution cannot proceed further and it deserves to be quashed. It is further canvassed that the Act has come into effect in the year 1940 and at that time it was not mandatory for the manufacturer to display his name and address on the carton of the drug however, since later it is made mandatory and therefore, it was incumbent on the part of the Drugs Inspector to forward one sample to the manufacturer in compliance of Section 23(4) of the Act. On these amongst other submissions, quashment of complaint is sought. To support contentions, she relied on following judgments :-

i) State of Maharashtra vs. Jawaharlal Shamlal Ujawane
1979 Mh.L.J. 50
ii) M/s Quixotic Healthcare & others vs. State of Maharashtra & another
2020 ALL MR (Cri) 1880.
iii) Laborate Pharmaceuticals India Ltd. and others vs. State of Tamil Nadu
AIR 2017 SC 2423.
iv) Lalankumar Singh & others vs. State of Maharashtra
Criminal Appeal No. 1757/2022
v) M/s Medicamen Biotech Ltd. & another vs. Rubina Bose
2008 ALL MR (Cri) 1768 (S.C.)

vi) M/s G. G. Nutritions and others vs. The State of Maharashtra and another
Criminal Writ Petition No. 1659/2022.

4. Learned APP opposed the said contention by pointing out that Section 23(4) of the Act does not contemplate sending of one part of the sample to the manufacturer but it specifically states that the part of the sample shall be sent to the person whose name, address and other particulars have been disclosed under Section 18-A of the Act. It is submitted that the person from whom the drug is seized, has declared under Section 18-A that he has received the said drug from M/s Relevium Pharma Pvt. Ltd. Aurangabad. Thus, the act only requires the Drugs Inspector to send the third sample to the person whose name was disclosed. It is further argued that Section 25(3) provides that if the analysis report is not objected within a period of 28 days from receipt of copy of the same, it becomes conclusive. Here in this case, petitioner No. 1 has failed to raise any objection to the said report within a period of 28 days and therefore, the report of the Government Analyst has become conclusive and hence question of compliance of Section 25(4) of the Act does not arise. Thus, according to him, it is not a case for quashment of the complaint. To support his submission, reference is

made to judgment of Hon'ble Apex Court in case of Amery Pharmaceuticals and another vs. State of Rajasthan in Appeal (Cri.) No. 300/2001.

5. Before considering the provisions of the Act as well as the precedents cited before the Court, it would be necessary to take into consideration the relevant factual matrix of the present case. It is not in dispute that on 31st May, 2021, Drugs Inspector drew sample of "SG Flames tablets" from batch No. GT200409 manufacturing date 03/2020 and expiry date 02/2022, manufactured by company for testing under Form No. 17. On 1st June, 2021, one part of the sample was sent to the Government Analyst, Aurangabad for testing. Report dated 12th November, 2021 was received stating that the drug is not of standard quality. Undisputedly, second portion of the sample was sent to M/s Pharma Seva Pharmaceuticals, the distributor from whom the drug was seized and to M/s Relevium Pharma whose name was disclosed to be the person from whom said drug was acquired. A letter was also issued to petitioner No. 1 on 1st December, 2021, with a copy of report of the Government Analyst. No reply was given by the petitioner of the said letter and hence another letter dated 27th December, 2021 came to be sent to this petitioner company. On 10th

January, 2022, company gave reply by acknowledging receipt of both letters. It is not claimed therein that letter dated 1st December, 2021 was not received. In fact the copy of said letter is annexed to the petition. In this letter the company was called upon to furnish self certified copies of documents stated therein for further investigation. In this reply it is claimed that analysis of sample showed that drug is manufactured in accordance with specification. Another letter dated 3rd February, 2022 was issued by company to Drug Inspector. Complaint came to be filed on 19th July, 2022. Summons was issued to petitioner No. 1 in December, 2022. the date of expiry of the drug in question was February, 2022.

6. There is no dispute about the fact that the person who drew the sample was duly authorised to do so under the Act. The Drugs Inspector is required to follow procedure at the time of drawing sample as contemplated by Section 23 of the Act. Section 23(4) makes it mandatory for the inspector to make four portions of the said sample. The relevant portion of Section 23(4) is reproduced as under :-

23 : Procedure of Inspectors :-

(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 18-A.

This provision clearly mandates that the Inspector on making four portions of sample, shall restore one portion thereof to the person from whom he takes it and out of remaining three portions, one portion be sent forthwith to Government Analyst for test or analysis. One portion shall be produced before the Court and remaining part shall be sent to the person if any, whose name, address and other particulars have been disclose under Section 18-A of the Act.

7. As far as present case is concerned, there is no dispute about the fact that the Inspector did make four portions of the sample drawn on 31st May, 2021. One was sent forthwith i.e. on 1st June, 2021 to the Government Drugs Analyst for analysis. Out of remaining three portions, one portion of sample was forwarded to M/s Pharma Seva Pharmaceuticals from whom the samples were drawn. One portion was produced before the Court at the time of filing of complaint. The fourth portion as provided by Section 23(4)(iii) of the Act, was sent to M/s Relevium Pharma Co. Ltd. the person whose name, address and other particulars have been disclosed under Section 18-A of the Act.

8. Section 18-A of the Act provides that 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. As per the complaint, name of M/s Pharma Seva Pharmaceuticals has disclosed name of M/s Relevium Pharma Pvt. Ltd from whom the said drug was procured. Thus, sending of sample to M/s Relevium Pharma Pvt. Ltd. is in compliance of the provisions of Section 23(4)(iii) of the Act.

9. It is sought to be contended by learned counsel for the petitioners that the Act has come into force in the year 1940 when there was no mandate for the manufacturer to display his name on the carton of the drug. Later on, which is made mandatory and hence it was incumbent on the part of the Drugs Inspector to send one portion of the sample to the manufacturer. Even for sake of arguments, it is accepted that for all practical purpose the manufacturer would be entitled to get one sample however, there is no provision appears in the act to that effect. Needless to state that it is not permissible for the Court to re-write the Statute and transgress the domain of the Legislature which may consider said aspect and effect amendment to the relevant provision, if so desire. At this stage, however, it cannot be held that merely because one sample was not sent to petitioner No. 1, there is non-compliance of provisions of Section 23(4) of the Act. More particularly, when there is compliance shown of sending samples to the person from whom it is drawn and also to the person who is named under Section 18-A of the Act.

10. One more aspect deserves consideration in this case is the mandatory provision of Section 25(3) of the Act which reads thus :-

> **25 Reports of Government Analysts** :-
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> (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 under section 18-A] 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.

11. This provision clearly shows that the report sent by the Government Analyst shall be evidence of the fact stated therein and such evidence shall be conclusive in nature unless the person from whom the sample was taken has within 28 days of receipt of copy of the report, notify in writing to the Inspector of the Court before which the proceedings in respect of sample are pending that he intends to adduce evidence in controversion of the report. As far as facts of the present case are concerned, it clearly shows that the report of the Government Analyst was sent to company by letter dated 1st December, 2021. This letter was not replied by company within 28 days raising its intention to adduce evidence in controversion of the

report. The company neither raised objection to report nor even called upon Drug Inspector to provide portion of drawn sample. Now question arises as to whether in such circumstances it was oepn for the company to raise challenge to the report during the proceeding before Magistrate. At this prima facie stage, this Court finds substance in the contention of learned APP that unless intention of the company was disclosed within 28 days of knowledge of report to it, the report of the Analyst has become conclusive. Though it is sought to be argued that the such letter was not received, however, bare perusal of the reply given by company does not indicate that the fact of receipt of letter along with report was disputed. Of course, it would be subject matter of trial to see as to whether the petitioner had received the said letter with copy of report of the Analyst or not.

12. As regards issue raised by petitioners about the drug being non pharmaceutical and that there is no prescribed method of analysis is concerned, neither definition of “drug” in Section 3(b) of Act nor Section 25(3) of the Act make any distinction between non-pharmacopial drug and other pharma drug. It might be open for company to canvas such issue during trial but certainly it does not become a ground for quashment of proceeding.

13. In the light of aforesaid facts and provisions of the Act, if the precedents cited supra in the case of Jawaharlal Ujawane is considered, then it is clear that it was a case wherein report of analyst was questioned successfully. In case of M/s Quixotic Healthcare (supra) this Court has recorded finding that within 28 days of the knowledge of the report accused raised objection about not agreeing with the report. In such circumstances, non-compliance of Section 25(4) of the Act was held to be fatal to the case of the complainant. Similarly, in the case of Laborate Pharmaceuticals (supra) sample was not sent to manufacturer though his name was disclosed under Section 18-A of the Act by person from whom sample was drawn. In present case, there is no non-compliance of mandatory provisions of Section 23(4)(iii). Hon'ble Apex Court in case of Lalankumar Singh (supra) was dealing with the case wherein manufacturer had called upon Drug Inspector to send sample for re-analysis. Moreover this is not case that there is no challenge raised to report within statutorily provided period under Section 25(3) of the Act. In case of M/s Medicamen Biotech (supra) manufacturer had challenged report within 28 days of receipt thereof. Finally in case of M/s g.G. Nutritions (supra) the report of analysis was given just 5

days before expiry date of drug and hence it was held that accused did not get opportunity to get sample re-analysed. In the instant case, however, the drug had expiry date of February 2022, whereas report was sent to company on 1st December, 2021. Thus, there was ample time available for company to seek re-analysis by raising objection to report. The company however chose neither to object report nor seek re-anaysis of sample. In considered view of this Court, above referred judgments have no application to the facts of present case.

14. Apart from this, it needs to be considered that complaint is not only filed against the company for manufacturing drug of 'not of standard quality' but also for non-supply of requisite information which is also an offence under Act. These issues since require evidence for its determination, this is not a fit case to quash the order of issuance of process and proceeding itself. Hence, petition stands dismissed.

15. It is clarified that all the aforesaid observations are made only for the purpose of deciding this petition and the Trial Court to decide complaint on its own merit.

16. Pending application, if any, does not survive and stands disposed of.

(R. M. JOSHI)
Judge

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Later on :-

After pronouncement of the order, learned counsel for the petitioner seeks continuation of interim relief for a period of six weeks.

Learned APP opposes the said request.

In order to enable the petitioner to challenge this order before the Hon'ble Apex Court, interim relief is extended for a period of six weeks from today.

(R. M. JOSHI)
Judge

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