



**IN THE HIGH COURT OF JUDICATURE AT BOMBAY,
NAGPUR BENCH, NAGPUR.**

CRIMINAL WRIT PETITION NO. 749/2025

1. M/s. Agron Remedies Pvt. Ltd.,
Sarverkhera, Moradabad Road,
Kashipur – UK 244731
(accused No.4)
2. Shri Mudit Agrawal,
Aged 48 yrs., Occ. Business,
Director of M/s Agron Remedies Pvt. Ltd.,
Sarverkhera, Moradabad Road,
Kashipur – UK 244731
(accused No.1)
3. Shri Narendra S/o Shankarlal Panchal,
Age 63 yrs., Occ. Service,
Manufacturing Chemist of M/s. Agron
Remedies Pvt. Ltd., Sarverkhera, Moradabad Road,
Kashipur – UK 244731
Present Address: M/s. Nuclotee Reemedies (P)
Ltd., Gadarpur (Udham Singh Nagar), Uttarakhand,
R/o. A/903 Shyamshikar Flat, Tolanka,
Bapunagar, Ahemdabad City, Gujarat-380024.
(accused No.2)
4. Shri Narendra Kumar S/o Shivraj Singh Jatau,
Age 41 yrs., Occ. Service, Analytical Chemist of
M/s. Agron Remedies Pvt. Ltd.,
Sarverkhera, Moradabad Road,
Kashipur – UK 244731
R/o. Amanpur, Kasganj, Amanpur,
Uttar Pradesh - 2072741
(accused No.3)

...PETITIONERS

VERSUS

1. State of Maharashtra at the instance of
Mr. M.V. Gotmare, Drug Inspector,
Office of Joint Commissioner, Food
and Drugs Administration (M.S.)
Javade Hospital, near Bus Stand, Amravati
(Orig. Complainant)
2. Commissioner, Food & Drug,
Administration, M.S. Surve No.34,
Bandra, Mumbai.

...RESPONDENTS

Ms. Rashmi S. Kulkarni, Advocate for petitioners
Mr. Bhagwan M. Lonare, APP for respondent Nos. 1 & 2.

CORAM : **M. M. NERLIKAR, J.**
DATE : **15.12.2025**

ORAL JUDGMENT :

Heard the learned counsel appearing for the
petitioners and the learned APP for respondents/State.

2. At the outset, the learned counsel for the petitioners
submits that the discharge application filed by the petitioners is
pursuing the wrong remedy. In-fact, the said remedy is not
available in summons case, therefore she does not press prayer

clause (B) of the petition. She presses prayer clauses (C) and (D) which read as under:-

“(C) Be pleased to quash and set aside the Criminal Complaint bearing R.C.C. No.53 of 2023 pending on the file of the learned Chief Judicial Magistrate, Amravati.

(D) Be pleased to quash and set aside the order issuing process dated 13.02.2023 passed below Exh.-1 in R.C.C. No.53 of 2023 pending on the file of the learned Chief Judicial Magistrate, Amravati.”

3. *The learned counsel for the petitioners submit that the order of issuance of process is a stamp order which shows non-application of mind. In-fact, when complaint was filed, it was expected from the Magistrate to apply the mind and by giving brief reasons order of issue process ought to have been passed. However, by passing the cryptic order, the Magistrate failed to apply his mind. The second contention raised by the learned counsel for the petitioners is that statutory right to defend the Government Analyst's Report is violated as the complaint was filed on 09.01.2023 i.e. after five months of the expiry of the shelf life of the Drug – Atrovastain-10 Tablets. She submits that the statutory right provided under Section 25(4) of the*

Drugs and Cosmetics Act (“the said Act”) has been violated, therefore she seeks quashing of the entire complaint and the proceedings. She further submits that the delay is also one of the important criteria which needs consideration as the report was received by the Drug Inspector on 25.07.2022 under Section 25(2) of the said Act and the application for referring the sample to the Central Drugs Laboratory (“CDL”) was made on 02.09.2022, which according to the petitioners were made after expiry of the shelf life of the drugs. Therefore, she submits that though the sanction order is dated 01.08.2022, however the complaint was filed on 09.01.2023 i.e. almost after five months of the sanction order. Under these circumstances, she submits that the Court ought not to have issued summons to petitioners as the valuable right under Section 25(4) of the said Act has been violated and further there was delay in filing the complaint.

4. On the other hand, the learned APP vehemently submits that the correct timeline was maintained by the Drug Inspector. The drugs were seized from Retail Outlet on 31.05.2022 and

the same was sent to the Government Analyst on the same day i.e. on 31.05.2022. The report dated 22.07.2022 was received by the Drug Inspector on 25.07.2022 and immediately it was sent to the petitioners on the same day itself, which was received by the petitioners on 28.07.2022. He further submits that the petitioners have replied to the same on 26.08.2022 and the reply was received by the Department on 30.08.2022. The sanction order was received on 01.08.2022 and thereafter, the complaint was filed on 09.01.2023. He submits that the time-line has been followed, therefore it cannot be said that the statutory right under Section 25(4) of the said Act is violated and accordingly, he prayed to dismiss the petition.

5. Upon hearing the rival contentions of the parties, three important questions are before this Court these are:-

- (I) whether the issue process order is in consonance with catena of judgments of the Supreme Court delivered from time to time,
- (II) whether there is infringement of the statutory right to defend the report of the Government Analyst and

(III) whether the sanction order was issued without giving opportunity to the petitioners or not.

6. So far as the first point is concerned, admittedly the process was issued without application of mind and filled blanks of the printed stamp. The Supreme Court in the case of **Lalankumar Singh and others Vs. State of Maharashtra, 2022 SCC Online SC 1383** has specifically dealt with order of issue process by relying on catena of judgments, wherein parameters have been laid down. The Supreme Court while considering the case of **JM Laboratories and Ors. Vs. State of Andhra Pradesh, MANU/SC?0124/2025**, has considered the case of Lalankumar (supra), wherein the Supreme Court has laid down the following guidelines:-

“37. Recently, a Bench of this Court to which one of us (Gavai, J.) was a Member, in the case of Lalankumar Singh and Others v. State of Maharashtra 2022 SCC On-Line SC 1383 (supra), has observed thus:

38. The order of issuance of process is not an empty formality. The Magistrate is required to apply his mind as to whether sufficient ground for proceeding exists in the case or not. The formation of such an opinion is required

to be stated in the order itself. The order is liable to be set aside if no reasons are given therein while coming to the conclusion that there is a prima facie case against the accused. No doubt, that the order need not contain detailed reasons. A reference in this respect could be made to the judgment of this Court in the case of Sunil Bharti Mittal v. Central Bureau of Investigation⁹, which reads thus:

“51. On the other hand, Section 204 of the Code deals with the issue of process, if in the opinion of the Magistrate taking cognizance of an offence, there is sufficient ground for proceeding. This section relates to commencement of a criminal proceeding. If the Magistrate taking cognizance of a case (it may be the Magistrate receiving the complaint or to whom it has been transferred under Section 192), upon a consideration of the materials before him (i.e. the complaint, examination of the complainant and his witnesses, if present, or report of inquiry, if any), thinks that there is a prima facie case for proceeding in respect of an offence, he shall issue process against the accused.

52. A wide discretion has been given as to grant or refusal of process and it must be judicially exercised. A person ought not to be dragged into court merely because a complaint has been filed. If a prima facie case has been made out, the Magistrate ought to issue process and it cannot be refused merely because he thinks that it is unlikely to result in a conviction.

53. *However, the words “sufficient ground for proceeding” appearing in Section 204 are of immense importance. It is these words which amply suggest that an opinion is to be formed only after due application of mind that there is sufficient basis for proceeding against the said accused and formation of such an opinion is to be stated in the order itself. The order is liable to be set aside if no reason is given therein while coming to the conclusion that there is prima facie case against the accused, though the order need not contain detailed reasons. A fortiori, the order would be bad in law if the reason given turns out to be ex facie incorrect.”*

Therefore, the Supreme Court in unequivocal terms, time and again has reminded the Courts that only if there exists sufficient grounds to proceed with the matter, process should be issued and before proceeding, the trial Court should adhere to the material placed before it and by applying the mind passed reasoned order. However, it appears from the order itself that the learned Magistrate has given a go-bye to all the parameters/guidelines laid down by the Supreme Court and passed one line order which is unseasoned, therefore, the order passed by the learned Magistrate is bad-in-law. Further, it is without application of mind and order is passed on printed stamp. This

practice is deprecated. If the order of issue process is itself is bad-in-law then further proceeding is vitiated.

7. It would be necessary to deal with another issue which was raised by the petitioners that their right to defend the Government Analyst's Report a statutory right which has been infringed as they were not able to send sample to the CDL, Kolkata in view of section 25(4) of the said Act and accordingly, the learned counsel for petitioners relied on ***M.Sea Pharmaceuticals Pvt. Ltd. & anr. Vs. The State of Maharashtra & anr., 2018 ALL MR (Cri) 3946***, wherein this Court has observed in paragraph Nos. 13 and 15 which read as under:-

“13. Therefore, taking into consideration ratio laid down in the case of Northern Mineral Ltd. [2010 ALL MR (Cri) 2593 (S.C.)] (supra), though that case was under the Insecticides Act, but the provision is pari materia. It was for the complainant to institute the complaint immediately and produce the sample with a request to the court to send the sample for analysis. It is to be noted that the reply was given to the show cause notice by the appellant on 31.08.2015. However, the complaint has been filed on 04.03.2016. The expiry of the sample extracted was 05/2016. Even on that day, if the complainant who would have presented the complaint itself ought to have pointed

out the said fact to the learned Chief Judicial Magistrate and made request to send the sample immediately or make the summons returnable before the period of expiry of the drug. No explanation has been given in the complaint, as to why inspite of receipt of notice reply dated 31.08.2015, the complaint was not filed immediately. On the contrary, it is stated in the complaint, that the controlling authority, Food & Drugs Administration, vide its letter dated 10.08.2015, had issued an order to enquire in the matter and launch a prosecution. That means, the sanction was obtained even before the reply was given by the applicants. The show cause notice was issued to the applicant on 05.08.2015 and the sanction was accorded on 10.08.2015. That be means, within 05 days, the sanction has been obtained. As per the ratio laid down in the case of Northern Mineral Ltd. [2010 ALL MR (Cri) 2593 (S.C.)] (supra), the valuable right of the appellant (in the present case, applicants) has been defeated and, therefore, the criminal prosecution against them is required to be dismissed.

“15. In Medicamen Biotech Ltd. & another [2008 ALL MR (Cri) 1768 (S.C.)] (supra) also, the Hon'ble Supreme Court has upheld the right of the accused persons under Sections 25(3) and 25(4) of the said Act. Here, in this case also, while issuing order of process, the learned Chief Judicial Magistrate has not considered what was the expiry date of the product of which sample was taken. Further, it is also to be noted that though the summons was made returnable for the accused persons on 29.06.2016 (which

was itself after the period a of expiry), accused persons were not served. Much time has been consumed to serve the accused persons. When the applicants have been deprived of their vital right, it cannot be the empty formality to face the trial. It would be the abuse of process of law and, therefore, inherent powers of this Court under Section 482 of the Code of Criminal Procedure, 1973, deserve to be invoked in view of the decision of the Hon'ble Supreme Court in the case of State of Haryana & others Vs. Ch. Bhajan Lal & ors. [AIR 1992 SC 604]."

Further reliance is placed on ***M/s. Theivendran and ors.***

Vs. State of Maharashtra & ors, MANU/MH/2594/2014

wherein the this Court has observed in paragraph Nos. 4 to 6 which read as under:-

"4. A perusal of Section 25(3) of the Drugs and Cosmetics Act, 1940 clearly shows that the report of Government Analyst shall be used as a conclusive proof unless the manufacturer within twenty-eight days of receipt of copy of the report, notified in writing the Inspector or Court before which any proceeding in respect of sample are pending that he intends to adduce evidence in contravention of the report. It has come on record that the applicants had intimated to respondent No.2 on more than one occasions that they did not agree with the report of Government Analyst. In the circumstances, what the court was required to do has been provided under Section

25(4) of the Drugs and Cosmetics Act, 1940. The court is under obligation to cause the sample of drug or cosmetic produced before it under sub-section (4) of section 23 of the Act to send for test or analysis. The Central Drugs Laboratory 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. As such in the present case, since the sample had already not been tested or analyzed by the Central Drugs Laboratory, it was required to be sent to the said laboratory by the Magistrate on its own accord or on the application made either by the applicants or by respondent No.2.

5. In the present case, as already stated by me, the applicants claim that the valuable right available to them under sub-section (4) of Section 25 of the Drugs and Cosmetics Act, 1940 has been infringed Inasmuch as the shelf value of the product was to get lost in the month of November 2011. Though the sample was collected on 30-9-2010 and Government Analyst's report was received on 24-2-2011 and though the applicants had disagreed with the report of Government Analyst, respondent No.2 had chosen to file the complaint on 31-10-2011. As such it is contended that even if the applicants wanted to avail their right under Section 25(4) of the Drugs and Cosmetics Act, 1940, the same was not available to them because the shelf value of the product was getting lost in November 2011.

6. *The learned Counsel has relied upon the judgment of the Hon'ble Supreme Court in the matter of Medicamen Biotech Limited and Another vs. Rubina Bose, Drug Inspector reported at MANU/SC/7327/2008: (2008) 7 SCC 196. In the said case, the Hon'ble Supreme Court had quashed the proceedings and had allowed the appeal filed against the order of the High Court. After having gone through the judgment relied upon by the applicants and after having considered the admitted facts, I have come to the conclusion that the valuable right available to the applicants under Section 25(4) of the Drugs and Cosmetics Act, 1940 has been infringed by respondent No.2 by filing the complaint on the last day of October 2011 in respect of the alleged sub-standard quality drug, the shelf value of which was getting lost in November 2011. It is abundantly clear that it was not possible for the applicants to make prayer to the learned Magistrate in the month of November 2011 to get the sample analysed from Central Drugs Laboratory. The steps, if any, taken either by the applicants or by the Court on its own accord were of no use in view of the expiry date of the product in question."*

Further reliance is placed on ***M/s. Medicamen Biotech Ltd. & anr. Vs. Rubina Bose, Drug Inspector, 2008 ALL MR (Cri) 1768 (S.C.)***, wherein the Supreme Court has observed in paragraph No.10 which read as under:-

“10. We find that this judgment helps the case of the appellant rather than that of the respondent because in spite of two communications from the appellant that it intended to adduce evidence to controvert the facts given in the report of the Government Analyst, the fourth sample with the Magistrate had not been sent for re-analysis. The observations in *Amery Pharmaceuticals's case* [2001 ALL MR (Cr1) 1980 (S.C.)] (*supra*) are also to the same effect. We find that the aforesaid interpretation supports the case of the appellants inasmuch they had been deprived of the right to have the fourth sample tested from the Central Drugs Laboratory. It is also clear that the complaint had been filed on the 2nd July, 2002 which is about a month short of the expiry date of the drug and as such had the accused appellant appeared before the Magistrate even on 2nd July, 2002 it would have been well nigh impossible to get the sample tested before its expiry. In the affidavit filed to the petition by Dr. D. Rao, Deputy Drugs Controller, and in arguments before us, it has been repeatedly stressed that the delay in sending of the sample to the Central Drugs Laboratory had occurred as the appellant had avoided service of summons on it till 9th May, 2005. This is begging the question. We find that there is no explanation as to why the complaint itself had been filed about a month before the expiry of the shelf life of the drug and concededly the filing of the complaint had nothing to do with the appearance of the accused in response to the notices which were to be issued by the Court after the complaint had been filed. Likewise, we observe that the

requests for retesting of the drug had been made by the appellant in August/September, 2001 as would be clear from the facts already given above and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for retesting well within time. We are, therefore, of the opinion that the facts of the case suggest that the appellants have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them.”

It would be necessary to consider Section 25(4) of the said Act which read as under:-

“25(1)...

(2)....

(3)....

(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.”

8. From the above ratio laid down by the Supreme Court, and this Court and after going through Section 25(4) of the said Act, it is clear that the statutory right provided under section 25(4) of the said Act is an important right and violation of the same results into vitiating the proceedings. The petitioners cannot be deprived of their valuable rights under Section 25(3) as well as Section 25(4) of the said Act. Further, in the present case after expiry of the drug, the Drug Inspector filed application on 02.09.2022 praying therein to summon petitioners for deposit of amount for sending sample to CDL, Kolkata for retesting. And therefore this action of Drug Inspector is unsustainable in law. In absence of report of the CDL, Kolkata, the prosecution ought not to have filed the complaint itself. However, without obtaining the report from the CDL, and filing complaint has led to deprivation of the right of petitioners from getting the sample tested before expiry of the shelf life of the drugs. In the opinion of this Court, the

entire proceedings is vitiated. Such violation has been sternly dealt by this Court in the case of **M/s. Unison Pharmaceutical Pvt Ltd. Vs. State of Maharashtra & ors**, (Writ Petition No.479/2023, decided on 03.10.2023), wherein this Court has observed in paragraph Nos. 19 to 21 which read as under:-

“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) Maharashtra M.S. Theivendran and Ors. Vs. State of 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.”

It appears that even in the present case, the Drug Inspector or the concerned authorities failed to perform their duty and without application of mind, the authorities have filed the complaint.

9. Admittedly, in the present case, the drug namely Atrovastain Tablets-10 was manufactured in the month of September 2020 and the expiry date was August 2022. It is further admitted position that the said drug was seized from Retail outlet on 31.05.2022 and the same was sent to the Government Analyst on 31.05.2022 i.e. on the same day. However, the report dated 22.07.2022 was received by the Drug Inspector on 25.07.2022, on the same day, the Drug Inspector has sent the report to the petitioner and the report was received by the petitioner on 28.07.2022. The petitioner replied and disagreed to the said report on 26.08.2022 which was received

by the Department on 30.08.2022 and the application was filed thereafter i.e. on 02.09.2022 by the Drug Inspector praying to summon the non-applicant (petitioners herein) for depositing necessary fees for sending sample portion to the CDL, Kolkata for retesting and to deposit the sample portion of the drug in the Court. It is to be noted that sanction order was issued on 01.08.2022 and the complaint was filed on 09.01.2023. From the aforesaid chronology of events, it could be gathered that the complaint was filed after expiry of the Drug's shelf life which was August 2022, therefore, it could be gathered that the complaint was filed only after expiry of the Drug's shelf life in order to deprive the valuable right provided under Section 25(4) of the said Act. It is further to be noted that the Drug Inspector ought not to have filed the complaint after expiry of the shelf life of the Drug, in the given eventuality as the petitioners were not able to exercise their rights contemplated under Section 25(4) of the said Act, however without application of mind, the complaint was filed, therefore the proceedings are vitiated.

10. The third point which was raised is in respect of sanction order accorded on 01.08.2022. The concerned authority failed to apply mind before granting sanction. However, it appears that the report was received from the Government Analyst to the Drug Inspector on 25.07.2022 and the report was sent along with sample on the same day i.e. on 25.07.2022 to the petitioners. Before receiving the reply from the petitioners, the sanction was granted. As could be gathered from the record that the petitioners have controverted the Analyst's Report by filing reply on 26.08.2022. Therefore, there was nothing before the Sanctioning Authority to consider the material as observed by this Court in case of M.Sea Pharmaceuticals Pvt. Ltd. (*supra*), *"the sanction was obtained even before the reply was given by the applicant. The show cause notice was issued to the petitioners on 05.08.2015 and the sanction was accorded on 10.08.2015, that means within five days, the sanction has been obtained. As per the ratio laid down in the case of Northern Mineral Ltd. Vs. Union of India (UOI) and anr. AIR 2010 SC 2829, the valuable right of the*

petitioner has been defeated, therefore the criminal prosecution against them is required to be dismissed.” Therefore, this Court in the aforesaid case has in specific terms observed that the Sanctioning Authority ought to have considered the reply of the petitioners and thereafter, by applying the mind, ought to have granted sanction. Even in the present case, merely on the basis of report of the Government Analyst, it appears that the Sanctioning Authority has accorded sanction. It is further to be noted that after according sanction dated 01.08.2022, the complaint was filed on 09.01.2023 which is almost after five months. There is no explanation from the Drug Inspector as to why he took five months to file the complaint before the Court, therefore as could be gathered from the entire facts and circumstances of the case, the complaint filed by the Drug Inspector is not maintainable in view of the fact that the right of the petitioners provided under Section 25(4) of the said Act is violated. For all these reasons, the petition succeeds, hence this Court passes the following order:-

ORDER

(I) Petition is allowed.

(II) Criminal Complaint bearing RCC No.53/2023 and the entire proceedings arising out of the said complaint pending on the file of the learned Chief Judicial Magistrate, Amravait is hereby quashed and set aside as well as the order of issuing process dated 13.02.2023 passed below Exh.1 in RCC No.53/2023 is also hereby quashed and set aside.

11. Petition stands disposed of in above terms.

(M. M. NERLIKAR , J.)

Gohane